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Gnilane Turpin

Carrie E. Lyons

Sidy Mokhtar Ndiaye

Nuria Gallego Marquez

Nika Elmi

See next page for additional authors

Authors

Gnilane Turpin, Carrie E. Lyons, Sidy Mokhtar Ndiaye, Nuria Gallego Marquez, Nika Elmi, Nguissali Turpin, Penda Dieng, Daouda Diouf, and Stefan Baral

report

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Project SOAR
Population Council
4301 Connecticut Ave, NW, Suite 280
Washington, D.C. 20008 USA
Tel: +1 202 237 9400
Fax: +1 202 237 8410
projsoar.org

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Leveraging Adaptive Implementation Strategies to Achieve Universal Coverage of Antiretroviral Therapy in Senegal

Gnilane Turpin,[1] Carrie Lyons,[1] Sidy Mokhtar Ndiaye,[2] Nuria Gallego Marquez,[1] Nika Elmi,[1] Nguissali Turpin,[2] Penda Dieng,[2] Daouda Diouf,[2] and Stefan Baral[1]

[1]Johns Hopkins University

[2]ENDA Santé

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Project team

Key investigators: Dr. Stefan Baral (Johns Hopkins University [JHU]), Daouda Diouf (ENDA Santé).

Key coordination and assistance team: Dr. Safiatou Thiam, Dr. Cheikh Bamba Guèye Dieye (CNLS), Penda Dieng, Daouda Diouf, Boubacar Diouf, Sidy Mokhtar Ndiaye, Benjamin Amay Sambou, Nguissali Turpin (ENDA Santé), Dr. Stefan Baral, Karleen Coly, Benjamin Liestman, Carrie Lyons, Sosthenes Ketende, Oluwasolape Olawore, Gnilane Turpin (JHU).

Key coordination and implementation team : Dr. Safiatou Thiam, Dr. Cheikh Bamba Guèye Dieye (CNLS), Pr. Cheikh Tidiane Ndour, Dr. Abdou Khoudia Diop (DLSI), Pr. Coumba Touré Kane (CHU Le Dantec), Dr. Ousseynou Ndiaye (CRCF), Dr. Aminata Leye (CS Pikine), Dr. Ibrahima Tito Tamba (CS Bignona), Dr. Ousseynou Cissé (CS Ziguinchor), Daouda Diouf, Nguissali Turpin, Dr. Fatou Maria Dramé, Sidy Mokhtar Ndiaye, Boubacar Diouf, Penda Dieng, Benjamin Amay Sambou, (ENDA Santé), Dr. Stefan Baral, Karleen Coly, Benjamin Liestman, Carrie Lyons, Sosthenes Ketende, Oluwasolape Olawore, Gnilane Turpin (JHU).

Primary Collaborators: Eileen Yam, Scott Geibel, Sherry Hutchinson, Deborah Weiss, Ellen Weiss (Population Council).

Field activities team : Sidy Mokhtar Ndiaye, Penda Dieng, Boubacar Diouf, Benjamin Amay Sambou (ENDA Santé), Karleen Coly, Benjamin Liestman, Carrie Lyons, Gnilane Turpin (JHU), Souleymane Sagna, Yaya Diedhiou, Aissatou Coly (CS Bignona), Dr Assane Ndiaye, Dr Aminata Sall, Dr Sokhna Sambarga Ciss, Massouda Dieng, Cheikh Bassirou Mbaye, Borso Mariama Ndiaye (CS Pikine), Jacques F Sambou, Jean Philippe Diatta (CS Ziguinchor), Khady Gueye, Chantal Faye, Coumba Sylla, Dr. Abdou Khoudia Diop (DLSI), Dr. Ousseynou Ndiaye (CRCF).

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ABBREVIATIONS AND ACRONYMS

ANRS	National Agency for AIDS Research—France
ART	Antiretroviral therapy
CD4	Cluster of differentiation 4
CM	Case management
FSW	Female sex workers
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HPTN	HIV Prevention Trials Network
mITT	Modified Intention to Treat
MSM	Men having sex with men
MSW	Male sex workers
MOH	Ministry of Health
PLHIV	People living with HIV
PWID	People who inject drugs
RCT	Randomized controlled trial
SOC	Standard of care
START	Strategic Timing of Antiretroviral Treatment
SVS	Sustained viral suppression
SW	Sex workers
UIC	Unique identifier codes
USAID	United States Agency for International Development
VS	Viral suppression

EXECUTIVE SUMMARY

INTRODUCTION

UNAIDS has identified the goals that by 2030, 95 percent of all people living with HIV (PLHIV) will know their HIV status; 95 percent of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART); and 95 percent of all people receiving ART will have viral suppression (UNAIDS 2014). A proposed strategy to achieve the 95-95-95 HIV treatment targets is through the rapid scale up of HIV treatment for all PLHIV, regardless of CD4 count or viral suppression (UNAIDS 2014).

Senegal represents a country that has been successful in the HIV response through early focus on prevention and the scale up of ART for PLHIV (Meda et al. 1999). HIV prevalence among reproductive age adults is relatively low at 0.5 percent, though a systematic review completed by our team highlighted the disproportionate burden of HIV among key populations, with 19.0 percent prevalence of HIV among female sex workers (FSWs) and 21.7 percent among men who have sex with men (MSM) (Papworth et al. 2013)]. Additionally, results from the HIV prevention 2.0 study, conducted in collaboration with Enda Santé in Dakar, Thiès, and Mbour, reported a 39 percent prevalence of HIV among trans women (Poteat 2017).

Senegal plans a rapid scale up of HIV treatment for all PLHIV, regardless of CD4 count or viral suppression. Results from HPTN 052,[1] START,[2] and Temprano[3] studies demonstrated the clinical benefit of early treatment. However, limited data exist on how to achieve sustained viral suppression (SVS) in real world contexts where significant barriers to effective ART delivery, uptake, and adherence persist. Thus, understanding the effectiveness of interventions around early initiation of ART and optimized retention is important for the continued HIV response.

The purpose of this study is to develop and assess the feasibility, fidelity, and cost-effectiveness of a universal coverage of ART intervention among PLHIV who are not virally suppressed in Dakar and Ziguinchor, Senegal. Specifically, this study aims to: 1) compare the effectiveness and durability of standard of care (SOC) versus individual case management (CM) programs to achieve SVS among PLHIV in Senegal; 2) characterize the acceptability of HIV self-testing (HIVST) by people at risk of HIV infection in Senegal, and determine if the promotion of self-testing increases the number of newly diagnosed PLHIV in clinic settings; 3) determine the cost-effectiveness of the universal treatment approach using the CM intervention; and 4) characterize the acceptability of iris scanning as a biometric follow-up strategy to enhance the measurement of follow-up and retention of PLHIV receiving ART care.

[1]HPTN 052 study: https://www.hptn.org/research/studies/hptn052

[2]START study: https://www.ninds.nih.gov/Disorders/Clinical-Trials/Strategic-Timing-Antiretroviral-Treatment

[3] Temprano study: https://clinicaltrials.gov/ct2/show/NCT00495651

METHODS

This study used an individual-level randomized controlled trial (RCT) to examine the impact of CM on viral suppression of PLHIV at 12 months compared to the SOC. A total of 596 participants were enrolled into the study, with 298 in both Dakar and Ziguinchor. To characterize self-testing and iris scanning, the number of PLHIV testing at specific referral clinics was compared before and after the implementation of self-testing, and implementation outcomes were assessed on the use of self-testing and iris scanning including uptake, routinization, acceptability, and long-term feasibility. The results of this study are intended to provide clearly articulated implementation plans for the use of HIVST approaches, CM interventions to improve retention in ART, and iris scanning to support measurement of retention in ART programs in Senegal.

Study sites included two government HIV treatment facilities in Ziguinchor and two in Dakar, due to the partnership between this study and the Senegal Ministry of Health (MOH). Participant enrollment into the study took place at the study sites, and study arms (SOC or CM) were assigned through individual randomization at the clinic level. Facility-level data were used to assess each HIV facility and determine the study site, in collaboration with Senegal MOH. The Government of Senegal made early treatment available for all PLHIV enrolled during this study, and the HIV self-test kits were procured through Project SOAR. However, the study supported the implementation of the CM intervention and the use of iris scanning as a biometric follow-up system for all enrolled in the study and the modification of the HIV self-testing kits based on feedback from consultations as to the appropriate design.

The study lasted 15 months from the time of the first participant enrollment to the last study visit. Each participant was part of the study for a maximum of 12 months. The cohort follow-up involved five study visits, lasting up to two hours each.

HIV self-testing

HIVST kits were distributed as an intervention, with the aim of increasing the number of new HIV diagnoses to drive testing yield in both arms of the study. The HIVST kits included an oral swab test stick and tube with solution, step-by-step instructions and HIV information booklets in French and Wolof, referral to an HIV health facility for confirmatory testing, and the study contact information.

in this phase of the study 1,839 HIVST kits were distributed. Of these, 1,149 individuals participated in the pre-test survey and from those, 817 individuals participated in the post-test survey. HIVST kit distribution took place during the first 6 months of enrollment into the study. HIVST kits were distributed to potential participants visiting the study sites and through partner organizations currently working with populations at increased risk for HIV. This study leveraged several methods for HIVST kit distribution including 1) supervised distribution, whereby HIVST kit-trained distributors provided pre-test instructions; 2) unsupervised distribution, relying on the written instructions and referral included in the self-test kit, without any additional supportive guidance; 3) venue-based distribution, implemented by partner organizations in sex work venues, bars, and nightclubs; and 4) network-based distribution, implemented by peer educators who received and distributed the HIVST to two other individuals using unsupervised distribution.

Individuals receiving the HIVST were asked if they wished to participate in a pre-and post-test survey. The survey collected information about demographic characteristics, socioeconomic status, behavioral characteristics, health and HIV treatment history, and HIV acquisition risks. It also collected information on HIV testing history, specifically recent use of HIVST. The post-test survey asked about implementation outcomes including the use of HIVST, HIVST results, acceptability, routinization, feasibility, and adoption.

Case management intervention

This study assessed the Senegalese SOC and CM, with the purpose of comparing the effectiveness and durability in achieving SVS among PLHIV in Senegal. The SOC for treatment support for PLHIV in Senegal included facility-based ART initiation and follow-up systems leveraging appointment books, though without active reminders. The CM intervention was a multi-step process to coordinate care and provide a family-like support system for PLHIV. Peer health navigators received a capacity building training in case management at each study site as part of the intervention. The training's goal was to reinforce their health navigation capacities, train them in case management, and provide them with the tools to adequately fulfill their role as new case managers.

After assignment of a case manager to each study participant, the approach had five key components: 1) initial meeting between person living with HIV and case manager; 2) follow-up meeting between case manager and participant; 3) biweekly automatic text messages sent to participant; 4) monthly phone calls from case manager; and 5) face-to-face meetings between case manager and participant every six months.

Recruitment and participant enrollment into the RCT took place at the health facility assigned as a study site. Self-testing kits were used to increase the number of potential study participants. Study participants were not excluded if not recruited through the self-testing kits. Trained health facility staff provided potential study participants with information and obtained informed consent from participants. Eligible participants completed a structured 1-hour interviewer-administered questionnaire, which served as the baseline assessment. Participants assigned to the CM intervention received SOC treatment CM support. All study visits took place at the study site and lasted approximately two hours each.

Baseline assessment of study participants included a questionnaire and biological testing. The baseline questionnaire assessed demographic characteristics, socioeconomic status, mobility and migration history, behavioral characteristics, health and HIV treatment history, and HIV acquisition risks. The baseline assessment also collected information on HIV testing history, specifically recent use of HIVST. For those who received an HIVST kit, there was significant attention placed on the measurement of implementation outcomes including the use of HIVST, HIVST results, acceptability, routinization, feasibility, and adoption. Follow-up involved visits at 3, 6, 9, and 12 months after the first visit. Questionnaires were administered at each visit. Questionnaires assessing behavioral characteristics, mental health, social support, and ART treatment adherence were administered at 6 months and 12 months. Abbreviated questionnaires were re-administered at three and nine months and assessed implementation outcomes

associated with HIVST and CM; the use of iris for tracking and engagement in ART services; and enacted, perceived, and intersectional stigma.

The data to assess the cost-effectiveness of the use of CM intervention were collected as part of this study. From the participant perspective, a standardized questionnaire based on the WHO's "Tool to Estimate Patients' Costs" was used to assess the cost to individuals in accessing and maintaining participation in CM. We also used two instruments: the brief version of the WHO Quality of Life instrument (WHOQOL-BREF) and the EQ-5D to assess participants' quality of life and health utility, respectively. The use of these two instruments enabled us to capture not only the indirect effects of such interventions on reducing HIV transmission, but also their direct effects on individuals' quality of life. Cost-related data were collected from the healthcare perspective as well, including (a) hiring and training of case managers; (b) monthly costs of preparing and delivering support through case managers; and (c) program implementation and oversight, including physical resources (e.g., office space), human resources, and overhead.

Biometric follow-up system

The biometric follow-up system intervention was conducted among participants in the CM and SOC cohorts. Iris scanning was used as a way to track participants and was focused on supporting evaluation of retention in ART. Preliminarily, the iris scanners and a laptop were placed in the study sites in Dakar and Ziguinchor, and all participants who initiated ART at these facilities had an iris scan as a means of registering into the study. The iRespond system was used for this study, including biometric scanners manufactured by CMITech. The image of the iris was not stored but rather was converted into a 12-digit numerical code, which was stored in the electronic health record. The iris was scanned at each study visit to identify the participant, and link the information obtained from the study visit to the previous information collected.

Iris scanning was a mandatory component for enrollment into the study, and therefore if a participant did not consent to the use of iris scanning, they were not enrolled into the study. Sample size and all associated calculations were the same for the biometric follow-up system as for the CM vs. SOC portions of the study.

RESULTS

HIV self-testing

From the 1,144 participants that completed the pre-test survey, 47 percent had never previously received an HIV test and were thus classified as first-time testers. Twenty-seven percent had had some history of HIV testing but had not been tested within the last 12 months, and only 26 percent had tested within the last 12 months.

A large proportion, 56 percent, of those identifying as men were first-time HIV testers. Women, meanwhile, were first-time testers in 39 percent of the cases. After adjustment, men were found to have 2.71 (2.08, 3.52) increased odds of being a first-time tester as compared to females. Thirty seven percent of participants who identified as key populations (male sex workers, men

who have sex with men, people who inject drugs, or trans women), reported never having been administered an HIV test Among female sex workers, the proportion of first-time testers was lower at approximately 21 percent, and the proportion that had tested within the last 12 months was 52 percent. Almost 63 percent of young adults (aged 18-24) were found to have never been administered an HIV test. Those aged 25–30 years were meanwhile found to be first-time testers 46 percent of the time, and those aged 31 and over were first-time testers 38 percent of the time. After an adjustment for region and sex, young adults had 2.84 (2.07, 3.90) increased odds of being a first-time tester when compared to participants aged 31 years and older.

Among the 877 individuals who participated in the post-test survey two weeks post-distribution, 94 percent reported having used the HIVST. Fifty-five percent of participants chose to use the test at the distribution site while 46 percent used it at home. Eighty-nine percent of participants reported that they had used the self-test kit within 2 days of the distribution date, but only 10 percent of individuals reported having sought confirmatory testing. A vast majority of participants, 95 percent, reported that they would recommend the HIVST kit to others. Overall, we found that use and acceptability of HIVST did not significantly differ between first-time testers and those with a previous testing history.

CM vs. SOC

The sample included 573 participants that were allocated to receive either standard of care (n=281) or the case management treatment (n=292). On average, participants were 36 years of age and the largest proportion (35%) had never attended school. Fifty-six percent of participants indicated that their sex at birth was female, and 57 percent identified as female at the time of the intervention. Among the SOC group, 21 percent of participants were sex workers while 24 percent were MSM. The proportion of these key populations was slightly smaller among the CM group, where 16 percent of participants were sex workers and 21 percent were MSM. Forty-three percent of SOC participants were on treatment at the outset of the intervention while a majority, 89 percent, had been newly diagnosed with HIV. In the CM group, 46 percent were on treatment and 85 percent were newly diagnosed.

In healthcare settings, only 9 percent of participants shared having ever avoided seeking healthcare because of their positive HIV status. No participant reported feeling mistreated or having been denied services by healthcare workers. Among the CM participants, 9 percent reported fear of being in public places, and 2 percent of had been blackmailed compared to 6 percent that were blackmailed in the SOC arm. In this study, the results show that out of 112 MSM surveyed at baseline, only 9 felt comfortable enough to talk about their sexual orientation with their family or friends. A few MSM participants, 14 percent (n=16), were often afraid to attend health facilities for their care needs, because of risk of stigmatization. This was more common among patients followed in standard care (19%) than those followed in case management (9%). Social stigma is the phenomenon most felt among FSWs in this study. In addition to stigmatization, FSWs also reported being survivors of violence. This violence takes the form of physical assault (15%), fear of going to public places (9%), verbal harassment (12%), blackmail (18%), and assault or sexual violence (24%).

The percentage of SOC participants indicating they never used a condom for sex with their principal partners over the past 30 days decreased from 33 percent to 16 percent between the baseline and fifth visit. In the CM group, meanwhile, 28 percent initially indicated they never used a condom with their principal partners over the past 30 days. This number decreased to 10 percent on the third visit and increased to 13 percent during the fifth visit.

Mental health was assessed using the Patient Health Questionnaire (PHQ-9). A score of 0–4 suggests minimal or no depression, 5–9 mild depression, 10–14 moderate depression, 15–19 moderately severe depression, and 20–27 severe depression. Between the first and fifth visit, the percentage of participants in the SOC arm with no depression increased from 64 percent to 87 percent. This trend was consistent for participants experiencing mild depression; this proportion decreased from 24 percent to 11 percent. Similarly, those experiencing moderate levels of depression decreased from 9 percent to 0.6 percent during the third visit, but increased to 2 percent during the fifth visit. Participants in the CM arm also displayed a decrease in the burden of depression between the first and fifth visit, with 65 percent of participants reporting no signs of depression at the first visit, 89 percent at the third visit, and a slight decrease to 84 percent at the fifth visit. At the first visit, 25 percent of participants in the CM arm experienced mild depression, 10 percent during the third visit, with a slight increase to 13 percent during the fifth visit. One percent of participants experienced moderately severe depression at the first visit, and no signs at the third and fifth visit.

The proportion of participants in the SOC arm who reported a very poor ability to take ART medication between the third and fifth visits increased from 0.6 percent to 3 percent. Those with a good ability to take ART medication averaged 37 percent, and those with an excellent ability decreased from 26 percent to 20 percent. In the CM arm, participants with a good ability increased from 26 percent to 27 percent, and those with an excellent ability similarly decreased from 36 percent during the third visit to 29 percent during the fifth visit.

When read the statement “I was satisfied with the case manager,” 33 percent of SOC participants responded that they strongly agreed and 60 percent that they agreed. In the CM group the numbers were 30 percent and 65 percent respectively. Ninety-five percent of SOC participants indicated that they either strongly agreed or agreed that they found the meetings with the case manager to be helpful, while 99 percent of CM participants had the same response. In both groups, a vast majority indicated that they either strongly agreed or agreed that they felt better equipped after the intervention (95% in the SOC group and 98% in the CM group). In regard to expanding the program to all PLHIV, 95 percent of the SOC group and 98 percent of the CM group either strongly agreed or agreed that meetings with a case manager should be made available to all PLHIV. The preference of patients wishing to continue to receive the support of case managers as was provided in the study, if available, is important. Eighty three percent of patients in standard care and 91 percent in case management would choose to continue with the support they received.

Viral suppression did not differ significantly according to randomized group at 6 months (77% in the SOC arm and 77% in the CM arm) and 12 months (74% in the SOC arm and 70% in the CM arm). There was no evidence of the durability of viral load suppression among 6-month responders continuing in both arms. While no participant characteristics were statistically

significantly associated with viral suppression at the 6-month visit, at the 12-month visit, moderate depression was negatively associated with viral suppression.

Iris scanning

Responses obtained from patients at inclusion in visit 3 and 5 show that more than 83 percent of the patients found the iris scanner comfortable or very comfortable to use, with a slight difference depending on the visit. In fact, the percentage of patients who thought it was acceptable or very acceptable increased from 46 percent at baseline to 94 percent at visit 5. Within the framework of this study, the evaluation of the acceptability of using iris scanners as a strategy for identifying and monitoring patients living with HIV was done at all visits. At baseline (n=49), visit 3 (n=115), and visit 5 (n=171), more than 90 percent of patients felt that the iris scanner was acceptable or very acceptable in their identification and follow-up. This rate of acceptability in identification for the CM participants is slightly higher at M6[4] (98%), then at M12 (93%) than at M0 (87%). Patient satisfaction with the use of the iris scanner was very high. More than 90 percent of them reported being satisfied or very satisfied with the use of the device. Those who were very satisfied were more numerous at M0 (25%), than at M6 (11%) and M12 (18%). As for acceptability of the iris scanner, more than 94 percent agreed to use it in the future.

CONCLUSION

This study was the first HIVST pilot study conducted in Senegal describing HIVST acceptability and feasibility for HIV testing in key populations. It was successful in reaching first-time testers, including a large proportion of men and young people, and people who did not traditionally access HIV services. These results have made it possible to define strategies for distributing HIVST to the populations most affected by HIV, including key populations, for various projects currently being implemented in Senegal and West Africa.

The intervention, through capacity building of case managers, aimed to improve patients' adherence to treatment, and hence viral load results. Although the study did not find a significant difference in the viral load results between the two arms at the end of the study, an improvement in viral load results was observed over time. Case managers remain essential in the follow-up and retention in care of PLHIV. Further analyses will be conducted to elucidate the factors associated with these outcomes.

The use of unique identifier codes for measuring patient retention remains essential in the context of HIV programs. Participants reported feeling comfortable using the iris scanner. It represents an alternative strategy in a context where key populations are hidden and mobile, allowing for better monitoring and also avoiding duplication of codes.

[4]M=Month

RECOMMENDATIONS

The results from the study demonstrate that HIVST provides a complementary approach to reach populations who may face barriers to engagement with existing and routine HIV testing services. These data suggest the potential impact that HIVST could have in complementing existing HIV testing services by reaching a diverse group of first-time HIV-testers as well as those who have not tested recently in Senegal. Preliminary results from this study guided the development of national HIVST guidelines. Senegal has moved forward with recommending it as an additional approach to testing priority populations, including key populations, based on the study's preliminary results

Among participants with a reactive HIVST, 58 percent went for confirmatory testing, and among those with an invalid test result, none went for follow-up testing. Follow-up in this context is a challenge. Implementation of HIVST should include specific strategies for confirmatory testing, thus ensuring effective linkage to care for newly HIV diagnosed individuals.

Patient monitoring in Senegal remains a challenge for the national ART program, especially during the agricultural season, with patients absent over a long period. Study participant follow-up was equally impacted, with participants not attending all study visits. Specific strategies to overcome this barrier could include strengthening of regional and cross-border referral and counter-referral systems between health facilities.

Case managers play a crucial role in participants' retention in care and sustained adherence to ART by providing navigational services and accompanying the patient throughout their journey. Continuous capacity building is recommended, with an emphasis on support, therapeutic education of the patient, and provision of adequate job tools.

While ART medication is provided free of charge in Senegal, the sites experienced stockouts of ART medication and viral load reagents, causing delays in treatment initiation and interruption. This component should be evaluated before any implementation of a Test and Start strategy.

Iris scanners represent an acceptable technology for PLHIV identification and follow-up in settings such as Senegal. Most participants reported being comfortable using them. Implementation should also include adequate training of staff on usage and development of appropriate communication before use with patients.

Participants reported having felt stigma from the community due to their HIV status. Communication strategies addressing HIV-related stigma, specifically through renewed investments in advocacy campaigns targeting opinion leaders, including the media and religious leaders, are needed to act on the social environment.

BACKGROUND AND RATIONALE

UNAIDS has identified the goals that by 2030, 95 percent of all people living with HIV (PLHIV) will know their HIV status; 95 percent of all people with diagnosed HIV infection will receive sustained ART; and 95 percent of all people receiving antiretroviral therapy (ART) will have viral suppression (UNAIDS 2014). A proposed strategy to achieve the 95-95-95 goals is through the rapid scale up of HIV treatment for all PLHIV, regardless of CD4 count or viral suppression (UNAIDS 2014). In Senegal, the government has initiated a process to collect different types of feasibility data that would inform an eventual national guideline adopting test and treat for all those living with HIV as a means of improving clinical outcomes and, ultimately, addressing the HIV epidemic. Since this approach has yet to be implemented in the Senegalese context, the data generated by this study would inform the utility of this approach in the local Senegalese context as well as guide implementation.

Senegal represents a country that has been successful in the HIV response through early focus on prevention and the scale up of ART for PLHIV (Meda et al. 1999). HIV prevalence among reproductive age adults is relatively low at 0.5 percent, though a systematic review completed by our team highlighted the disproportionate burden of HIV among key populations, with 19 percent prevalence of HIV among female sex workers (FSWs) and 22 percent among men who have sex with men (MSM) (Papworth et al. 2013). In an effort to continue mitigation of the HIV epidemic, the government of Senegal has communicated plans to USAID as well as proposed investigators here for a rapid scale up of HIV treatment for all PLHIV, regardless of CD4 count or viral suppression.

At the 2015 IAS meeting in Vancouver, updated HPTN 052 data demonstrated that the preventive benefit of treatment in serodiscordant couples is maintained over time with sustained viral suppression (SVS), with 93 percent benefit for genetically linked transmissions. However, when evaluating all transmissions, including those acquired from sexual partners outside of the primary partnership, the efficacy was reduced to 67 percent (HPTN 2015). Data from the Strategic Timing of Antiretroviral Treatment (START) study also demonstrated the clinical benefit of early treatment for those living with HIV (NIH 2015). Lastly, the ANRS Temprano study demonstrated the same benefits of early treatment with tuberculosis prophylaxis for PLHIV in Cote d'Ivoire (Danel et al. 2015). While these three studies reinforce the importance of treatment, there remain limited data on how to achieve SVS in the real world, with significant barriers to effective ART delivery, uptake, and adherence. In the context of the HIV epidemic in Senegal, with a disproportionate burden of HIV among key populations, understanding the effectiveness of interventions around early initiation of ART and optimized retention is important for the continued HIV response.

HIV SELF-TESTING

HIV self-testing (HIVST) is emerging as an important tool to promote HIV screening and, potentially, to increase frequency of HIV testing in at-risk populations for whom more frequent

testing is recommended (WHO 2014). In many places, there is stigma associated with seeking HIV testing. For key populations, in particular, requesting an HIV test regularly may be perceived by clients or healthcare providers as disclosing a stigmatized behavioral risk. Self-testing can potentially overcome these barriers to HIV testing uptake by placing the locus of control of testing on the individual, increasing confidentiality, and allowing members of stigmatized groups to test in settings with privacy, safety, and dignity. Self-testing has become possible as HIV rapid tests have grown more sensitive, and devices have become less complex, enabling testing in field settings. There are a number of possible device options that could be used in an HIV self-testing program. While the majority of the work has taken place in higher income settings (Sharma et al. 2014), emerging work from low- and middle-income countries has shown similar acceptability and comprehension of the materials, supporting the use of self-testing. Consequently, there are HIVST products that were developed by companies in France (Autotest VIH, AAZ), United Kingdom (Biosure HIV Self-Test), and in the United States (OraQuick In-Home HIV Test, OraSure Technologies). There are also specific policies for licensure and registration in the United States and United Kingdom, with more countries having policies in place explicitly allowing HIVST including Australia, France, Hong Kong, Kenya, and South Africa. Far more countries have policies under development including several sub-Saharan African countries, though there are no West and Central African countries in this list yet. Several interesting analyses have taken place, including the "Acceptability and feasibility of a novel approach to promote HIV testing in sexual and social networks using HIV self-tests," presented by Dr. Harsha Thirumurthy at the IAS 2015 Meeting in Vancouver, which demonstrated good uptake of self-testing and the ability to distribute these tests through social networks. This approach leveraged the semi-restricted model of distribution, though having broader open access is also an accepted approach, as is more clinically restricted approaches whereby HIVST would take place in health facilities. In studies in Malawi, the highest uptake of HIVST was among adolescents, with high levels of return of questionnaires distributed, and self-testers included a large number of first time HIV testers (Figueroa et al. 2015). While HIVST had not been formally promoted by the Senegalese government when the study was introduced, the Ministry of Health (MOH) was interested in evaluating the potential of this approach in this study setting to boost numbers of newly diagnosed people.

CASE MANAGEMENT VS. STANDARD OF CARE

Case management (CM) is a multi-step process to coordinate care and provide a family-like support system for PLHIV. This approach involves the assignment of a case manager to a patient with the goal of providing health care and supportive services navigation, adherence counseling, and tailored support for care engagement and treatment adherence. CM approaches build on cognitive behavioral theory and help address barriers to treatment uptake, adherence, and retention by working with individuals to set treatment goals, build treatment literacy and self-efficacy to execute treatment plans, and provide social and logistics support to patients to achieve their goals (Wall et al. 2015). CM approaches have been successfully employed by nurses, social workers, and HIV counselors for individuals living with HIV (Farley et al. 2014). In South Africa, CM interventions for different populations, including those co-infected with HIV and tuberculosis, pregnant women living with HIV, and FSWs at risk for and living with HIV, have been broadly used

(Schwartz et al. 2105; Clouse et al. 2015). CM approaches build on long experience of using ancillary health workers to support medication adherence among those living with HIV (Kenya et al. 2014; Chamie et al. 2014). The CM approach proposed in this study will adapt the MyLife, MyChoices, MyCare, and MyHealth model being used by PI-Baral and others in a HIV Prevention Trials Network study among MSM (HPTN 078) (Farley et al. 2014).

BIOMETRIC FOLLOW-UP SYSTEM

Unique identifier codes (UIC) are an essential component of measuring retention in health services. National health identifiers are often used, but are often challenged by limited uptake at the local clinic level. Biometric measures, such as digit fingerprinting, have been used in a variety of settings including the Sex Work Outreach Program in Kenya as well as more recently for a cohort of sex workers in Zambia. Fingerprint-based biometrics have also been used in HIV programming in Uganda and in the US (Chamie et al. 2014; Cohen et al. 2012). In all cases, the acceptability has been relatively high among those at high risk for HIV. However, there have been challenges in the implementation of digit fingerprinting, as well as legitimate privacy concerns. In 2012, there were discussions about the use of digit fingerprinting for a study in Senegal, and at that point it was deemed problematic. However, at that time, the studies were focused on HIV prevention, and UIC leveraging reproducible anonymous codes were deemed acceptable. Due to interest in assessing biometric measures, as well as the concerns around stigma relating to digit fingerprinting, iris scanning has been adopted for this study's biometric measure. Iris scanning has been used in Guinea during the Ebola outbreak in 2015, in Burma with HIV patients through Population Services international, in Kenya related to HIV among key populations, and in Thailand in partnership with the MOH. Given the increasing focus on ART and the significant importance in measuring loss to follow-up in treatment studies, biometric UIC are an important component of the follow-up plan of this study. The discussions with the Senegalese MOH in 2015 highlighted enthusiasm about the use of biometric measures, and conversations with the MOH in 2016 highlighted interest around iris scanning as a biometric follow-up system.

OBJECTIVES AND STUDY AIMS

The overarching goal of this study is to assess the feasibility, fidelity, and cost-effectiveness of a universal coverage of ART intervention among individuals living with HIV who are not virally suppressed in Dakar and Ziguinchor, Senegal.

- **Specific Aim 1:** Characterize the acceptability of HIVST by people at risk of HIV infection in Senegal, and determine if the promotion of self-testing increases the number of newly diagnosed PLHIV in clinic settings.
- **Specific Aim 2:** Compare the effectiveness and durability of the existing standard of care (SOC) in Senegal versus individual CM programs to achieve SVS among PLHIV in Senegal.
- **Specific Aim 3:** Determine the cost-effectiveness of the universal treatment approach using the CM intervention.
- **Specific Aim 4:** Characterize the acceptability of iris scanning as a biometric follow-up strategy to enhance the measurement of follow-up and retention of PLHIV receiving ART care.

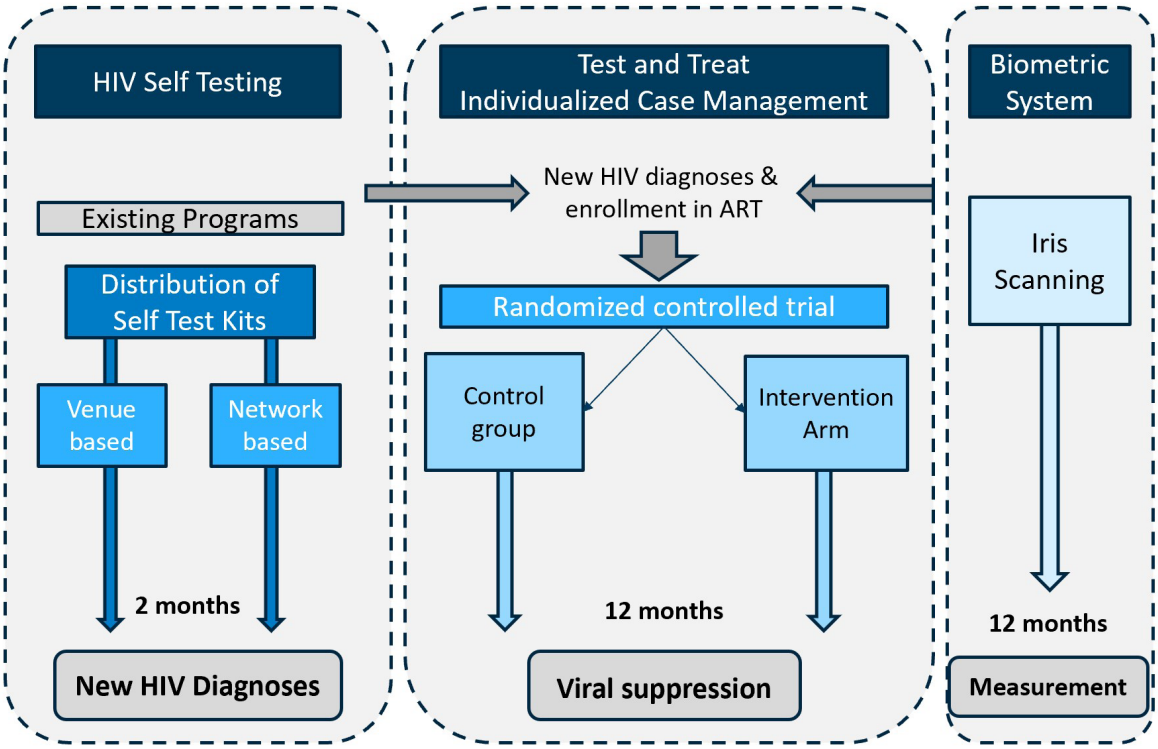
STUDY OVERVIEW

This study was structured as a randomized controlled trial (RCT) that used an effectiveness-implementation hybrid design to test the effectiveness and durability of CM interventions in achieving SVS among PLHIV who are not virally suppressed. CM vs. SOC approaches were assessed using an individual-level RCT of case management to improve viral suppression of those living with HIV at 12 months compared to the Senegal SOC. While viral suppression was a primary outcome of this intervention, significant attention was given to the collection of service and implementation outcomes to assess both the SOC and CM. The secondary aim of this study was to characterize acceptability of HIVST and iris scanning for the diagnosis and retention in ART among those living with HIV.

Since test and treat has not yet been evaluated in the Senegalese context, the results of this study will improve the understanding of the effectiveness of this intervention and inform the roll out of this national strategy. These results are intended to provide clearly articulated implementation plans for the use of HIVST approaches in Senegal, CM interventions to improve retention in ART, and iris scanning to support measurement of retention in ART programs. We will provide details regarding who delivers the intervention, the setting of the intervention, the dose and frequency of the intervention, and outcomes of the intervention. Combining the primary outcome of SVS with additional implementation outcomes, including acceptability, fidelity, appropriateness, routinization, and sustainability, is an innovation in measuring the potential utility of this approach. The primary outcome of effectiveness here is a binary outcome of SVS. One innovation includes the integration of implementation research outcomes with the effectiveness outcome to interpret results in the context of how these data can inform real-world HIV programs. Thus, several well-established implementation measures, including

appropriateness, fidelity, sustainability, and implementation costs, will be measured during the course of the study (Procter et al. 2011).

Figure 1 Study overview



CONTEXT AND SITES

Study sites included two government HIV treatment facilities in Ziguinchor, and two in Dakar. Participant enrollment into the study took place at the study sites, and study arms (SOC or CM) were assigned through individual randomization at the clinic level. Notably, the HIV treatment facilities are existing government facilities, due to the partnership between this study and the Senegal MOH.

Monitoring and evaluation data collected by the Senegal MOH were shared with our team to help assess the current patient flow in the health facilities. The current number of patients living with HIV under care in government HIV facilities was approximately 5,583 in Dakar and 2,005 in Ziguinchor. Among new patients receiving HIV tests, 35 percent were men and 65 percent were women. The number of new positive HIV diagnoses was approximately 125 individuals per week in Senegal. There were seven HIV facilities in Dakar and two in Ziguinchor, which were assessed for study site selection. Facility-level data were used to assess each HIV facility and determine the study site, in collaboration with Senegal MOH.

The Government of Senegal made early treatment available for all PLHIV enrolled during this study, and the HIVST kits were procured through Project SOAR. However, the study supported

the implementation of the CM intervention and the use of iris scanning as a biometric follow-up system for all enrolled in the study and the modification of the HIV self-testing kits based on feedback from consultations as to the appropriate design.

AIM 1: HIV SELF-TESTING

Overview

HIVST kits were distributed as an intervention, with the aim of increasing the numbers of new HIV diagnoses to drive accrual into both arms of the study. Self-testing kits were distributed as a means of facilitating recruitment into the study by increasing the number of potential study participants visiting the study sites during the enrollment period. The approaches also utilized supervised or unsupervised distribution of the HIVST.

HIV self-test kits

The HIVST kits include:

1. Written, step-by-step instructions on the correct use of the self-test.
2. An oral swab test stick and tube with solution.
3. Information booklets on HIV and testing.
4. Educational information about the test.
5. Referral to an HIV health facility for confirmatory testing.
    a. For those who test positive with the HIVST kits, the referral provided inside the kit will direct the individual to a study site in order to facilitate the linkage to ART.
    b. Referral cards will either be a sticker or a small card containing the information for both study sites in the respective city.
6. A phone number is provided on the HIV self-test kit referral card. This is the phone number of the study coordinator, and the participants are encouraged to call this number with any questions or information for referrals.

The instructions included in the kit are provided in French and Wolof, and adapted to the Senegalese context. For those who test positive with the HIVST kits, the referral provided inside the kit directs the individual to a study site in order to facilitate the linkage to ART.

OraQuick HIV Self-Test Kits are used for the HIVST in this study. OraQuick is manufactured by Orasure Technologies, Inc (www.OraSure.com). Clinical studies have estimated that the sensitivity of the OraQuick In-Home HIV Test is 92 percent, meaning that 92 percent of the results will be positive when HIV is present. Clinical studies have also shown that OraQuick In-Home HIV Test has a specificity of 99.98 percent, representing the percentage of results that will be negative when HIV is not present. The United States Food and Drug Administration has issued a premarket approval for the Oraquick In-Home HIV test: http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm311895.htm

Participants and recruitment

This study focused on researching populations with a disproportionate burden of HIV and individuals who do not seek/agree to HIV testing in the health facilities. HIVST kits were distributed through partner organizations currently working with populations at increased risk for HIV. This includes associations and organizations working with MSM, FSWs, trans women, and people who inject drugs (PWID). The HIVST distribution was led by Enda Santé, an organization with extensive experience working in these communities.

In this phase of the study 1,839 HIVST kits were distributed. A total of 1,149 individuals participated in the pre-test survey, and from among those, 817 individuals participated in the post-test survey.

Inclusion criteria

- 18 years of age or older
- Mentally sound and capable of providing consent to participate
- Agrees to complete HIV self-test
- Speaks either French, Wolof, or both
- Provided informed consent to participate in the survey

Exclusion criteria

- Under 18 years of age
- Demonstrates mental incapacity, under the influence of substances, or any other illness preventing comprehension of the study procedures and informed consent
- Does not agree to complete HIV self-test
- Has not provided informed consent to participate in the study

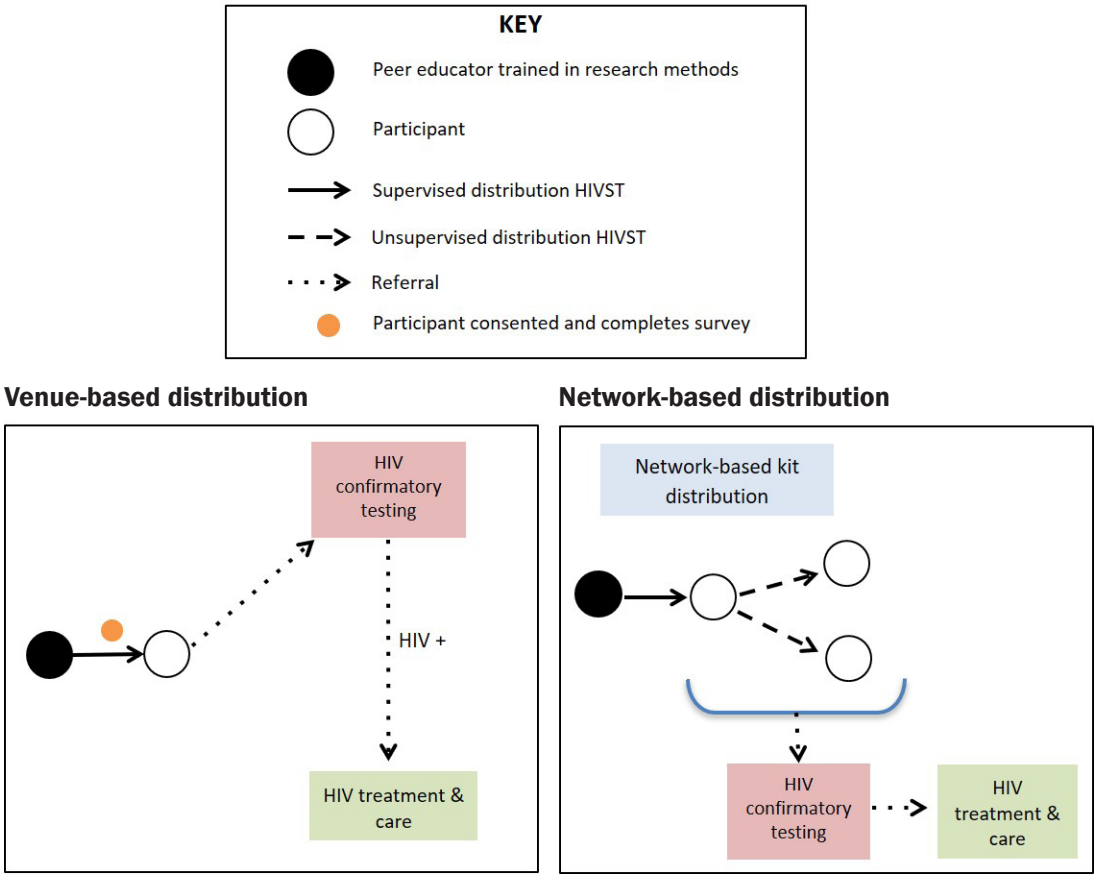
Recruitment process

HIVST kits were distributed as an intervention, with the aim of increasing the numbers of new HIV diagnoses to drive accrual into both arms of the study. Self-testing kits were distributed as a means of facilitating recruitment into the study by increasing the number of potential study participants visiting the study sites during the enrollment period. This study leveraged several methods for HIVST kit distribution:

- **Supervised distribution:** HIVST kit-trained distributors provided pre-test instructions, including education on proper HIVST kit use and the importance for confirmatory testing, irrespective of result. The participant is informed that the HIVST is considered a screening test, and not meant to be used as a replacement for HIV testing at the health clinic. Peer educators are present to demonstrate the correct use and analysis of the test kits. In addition, participants are offered optional pre-test counseling, separate from the pre-test instruction information. Upon completion of testing, participants have the option to disclose the result to the distributor and receive post-test counseling if desired.

- **Unsupervised distribution:** The unsupervised distribution relies on the written instructions and referral included in the self-test kit, without any additional supportive guidance, pre-test instructions, or demonstration of the self-test.
- **Venue-based distribution:** Venue-based HIVST kit distribution is implemented by partner organizations. Venue-based approaches for distribution target high-risk, and hard to reach populations. Target venues include sex work venues, bars, and nightclubs. Using the supervised distribution approach, peer educators provide individual instruction and training of HIVST kits. The participants receive the same guidance as highlighted under the supervised distribution approach.
- **Network-based distribution:** The individual receives a test kit from the peer educator then distributes the HIVST to two other individuals using unsupervised distribution, which provides no verbal instruction or demonstration. The participant is encouraged to distribute the additional test kits to sexual partners or friends. In this study, the individual receiving the HIVST kits participates in supervised distribution and is provided with verbal description of use of the test and a demonstration.

Figure 2 Distribution approaches



Venue-based HIVST kit distribution was implemented by partner organizations and led by Enda Santé, who has extensive experience working in these communities, including providing services in venues and working with venue managers when applicable. This approach utilizes supervision

distribution of HIVST kits to distribute to high-risk and hard to reach populations, including men who have sex with men, female sex workers, trans women, and people who inject drugs. Target venues include sex work venues, bars, and nightclubs. Trained peer educators with experience in venue-based service provision led the distribution of HIVST. In venue locations, trained peer educations worked with venue managers, when applicable, and other peers to determine a location for HIVST kit distribution. Additionally, peer educators worked with each venue or site to specifically determine whether to approach individuals for recruitment, or to make the HIVST distributors available in the venue for potential participants to approach study staff for participation.

Distribution was conducted by trained Enda Santé peer educators, who provided brief instructions to each individual receiving a kit. The pre-test instructions include education on proper HIVST kit use, as well as the importance for confirmatory testing, irrespective of result. The individuals were informed that the HIVST is considering a screening test, and not meant to be used as a replacement for HIV testing at the health facility.

HIVST kits were also distributed using a network-based approach. The social network-based approach is focused on providing a primary recipient with one HIVST kit for themselves, and two additional test kits to distribute to individuals within their network. Social network-based distribution leveraged venue-based distribution to engage the primary HIVST recipient, who received the HIVST kits directly from the trained distributor. The primary recipient then distributed to secondary receipts through indirect, unassisted/unsupervised distribution; secondary recipients only received written instructions and information contained within the HIVST kit. The individual receiving the HIVST kits was encouraged to distribute the additional test kits to sexual partners or friends.

Participation in the pre- and post-test survey was optional, and individuals were provided the HIVST kit regardless of participation. No information was collected from individuals not willing to participate in the study questionnaires.

Consent process

Individuals receiving the HIVST were asked if they wished to participate in a pre-and post-test survey. Individuals were informed that participation was voluntary, and they would receive the HIVST kit regardless of their participation in the survey. Using a consent script approved by the Johns Hopkins School of Public Health Institutional Review Board and the Comité National d'Ethique pour la Recherche en Santé in Senegal, the study staff explained the study, outlining the purpose, sequence of events, rights, and potential risks and benefits before beginning any research activities with the participant. The consent form was translated to French and Wolof by translators not affiliated with the study and back-translated to ensure accuracy. A paper copy of the consent form in French was available should any participant want to keep one for personal records.

Individuals who did not complete their HIVST on site were asked to provide a phone number and/or email address for the study staff to use for the follow-up survey. Participants were informed of the process and that call history and numbers are deleted after a call has been made.

Children and adults lacking capacity to consent were considered ineligible to participate in the study, therefore we did not obtain a legally authorized representative's signature.

Study implementation and data collection

HIVST kits were distributed through venue-based approaches and network based-approaches as described in the recruitment process. The instructions included in the kit were provided in French and Wolof, and adapted to the Senegalese context. For those who tested positive with the HIVST kits, the referral provided inside the kit directed the individual to a study site in order to facilitate the linkage to ART.

Individuals receiving the HIVST were asked during the distribution if they wished to participate in an optional pre-and post-test survey. The pre-test survey was conducted at the venue of distribution, in a private room, and by a trained interviewer. The post-test survey was conducted over the phone two weeks after the kit was distributed.

The survey collected information about demographic characteristics, socioeconomic status, behavioral characteristics, health and HIV treatment history, and HIV acquisition risks. This also collected information on HIV testing history, specifically recent use of HIVST. The post-test survey asked implementation outcomes including the use of HIVST, HIVST results, acceptability, routinization, feasibility, and adoption.

Self-testing was not documented for all individuals who presented at the government health clinics. However, clinicians assessed the reasons for confirmatory testing, though this was not documented unless the people chose to enroll into the RCT study. If enrolled into the study, the baseline assessment administered included question on HIVST knowledge and use.

HIVST kit distribution took place during the first six months of enrollment into the study. No personal Identifier was collected during the distribution of HIVST kits. A unique idenitifier code (UIC) was generated for each participant and was constructed using information known only to them. The code was formulated in consultation with members of the target populations through a recently implemented study in Senegal (IRB00005832) to contain questions that are easily answered, reproducible, culturally appropriate, individually unique, and that members of the target populations will be comfortable answering. During the process of creating the unique ID code with the participant, the study team member indicated that they only needed to respond with the appropriate number(s) or letter(s) to the question and do not need to give the full response (e.g., participant only need to provide the first letter of the city, rather than state the full name of the city). Doing so enables an additional sense of privacy for the participants.

The UIC was constructed as follows:

L_1	L_2	L_3	L_4	N_1	N_2	N_3	N_4	L_5	L_6

L=Letter N=Number

Example: *AAAA0101AAA*

1. What are the first two letters of the city/town in which you were born? (L_1L_2)
2. What are the first two letters of the month in which you were born? (L_3L_4)
3. How many living brothers from the same mother do you have? (*use 0# or 00 for less than ten or zero brothers from the same mother, respectively*) (N_1N_2)
4. How many living sisters from the same mother do you have? (*use 0# or 00 for less than ten or zero sisters from the same mother, respectively*) (N_3N_4)
5. What are the first two letters of the neighborhood in which you currently live? (L_5L_6)

Data analysis

Implementation outcomes were used to assess the use of self-testing including uptake, routinization, acceptability, and long-term feasibility. Multiple broadly accepted indicators were used for each of these determinants of implementation. Specifically, implementation results were assessed to inform the use of rapid-kit-based self-testing as a strategy of finding new PLHIV that are not testing via traditional approaches.

Demographic characteristics, HIV testing history, and HIV risk behaviors were analyzed from pre-test questionnaires. Use and acceptability of HIVST was determined from post-test results. Pre- and post-test results were analyzed separately to understand crude estimate and prevalence among the pre- and post-test study populations. The pre- and post-test data were linked through the UIC of the participant.

To assess self-testing for potential increase in HIV diagnosis in the health facilities, we conducted a pre/post assessment to compare numbers of individuals presenting with new diagnoses to specific referral clinics before and after the implementation of self-testing. Measurement of individuals presenting with new diagnoses prior to self-testing distribution was obtained through historical facility health records. Pre/post assessment also included implementation outcomes to assess confirmatory testing and linkage to care.

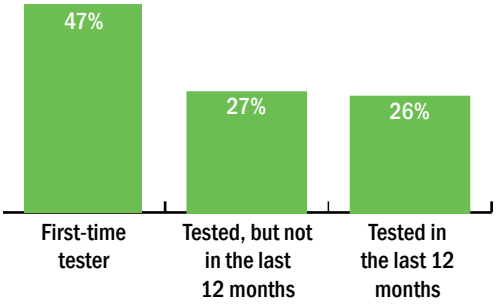
Logistic regression was used to assess the crude relationship between HIV testing history (first-time vs. previous testers), demographic characteristics, and HIV risk behaviors. Multiple multivariable logistic regression models were developed to separately assess each demographic characteristic, HIV testing history, and HIV risk behaviors as primary predictors of first-time testers and adjusted for a priori demographic characteristics. Pearson's Chi squared tests were used to assess the crude relationships between first-time testers and HIVST use and acceptability, as well as the relationships between self-reported HIVST result and use and demographic characteristics. A significance value of $p < 0.05$ was used for all analyses.

Results

Baseline characteristics: Pre-test survey results

From the 1,144 participants that completed the pre-test survey, 47 percent had never previously received an HIV test and were thus classified as first-time testers. Twenty-seven percent had had some history of HIV testing but had not been tested within the last 12 months, and only 26 percent had tested within the last 12 months (Figure 3).

Figure 3 HIV testing history among study participants



Furthermore, we analyzed HIV testing histories among self-reported key populations (n=370) including FSW, male sex workers (MSW), MSM, PWID, and trans women (Table 1). Approximately half of participants who identified as MSM, MSW, PWID, or trans women reported never having been administered an HIV test. Among female sex workers, the proportion of first-time testers was lower at approximately 21 percent, and the proportion that had tested within the last 12 months was 52 percent. This was expected given the legalization of sex work sex work and institution of a registration system dependent on annual HIV testing.

Table 1 HIV testing history among key populations

Self-reported key population[x]	Total		HIV testing history						
			First time tester		Yes, but not in the last 12 months		Yes, within the last 12 months		
	n/N	%	n/N	%	n/N	%	n/N	%	p-value
Key population (any)									<0.001
Yes	370/1149	32	136/370	37	103/325	28	131/325	35	
No	779/1149	68	400/774	52	205/774	27	169/774	22	
Sex worker (all genders)									<0.001
Yes	204/1085	19	54/204	27	53/204	26	97/204	48	
No	881/1085	81	450/878	51	240/878	27	188/878	21	
Female sex worker									<0.001
Yes	155/1085	14	32/155	21	43/155	28	80/155	52	
No	930/1085	86	472/927	51	250/927	27	205/927	22	
Male sex worker									0.239
Yes	48/1085	4	22/48	46	9/48	19	17/48	35	
No	1037/1085	96	482/1034	47	284/1034	28	268/1034	26	
Men who have sex with men									0.923
Yes	174/1149	15	80/174	46	49/174	28	45/174	26	
No	975/1149	85	456/970	47	259/970	27	255/970	26	
People who inject drugs									0.184
Yes	42/1131	4	25/42	60	7/42	17	10/42	24	
No	1089/1131	96	500/1084	46	297/1084	27	287/1084	27	
Transgender women									0.242
Yes	20/1148	2	11/20	55	7/20	35	2/20	10	
No	1128/1148	98	525/1123	47	300/1123	27	298/1123	27	

The study also analyzed the relationship between demographic characteristics such as age and sex at birth and being a first-time tester (Table 2). We observed that a large proportion, 56 percent, of those identifying as men were first-time HIV testers. Women, meanwhile, were first-time testers in 39 percent of the cases. After adjustment, men were found to have 2.71 (2.08, 3.52) increased odds of being a first-time tester as compared to females.

When analyzing participant testing rates by age, almost 63 percent of young adults (aged 18–24) were found to never having been administered an HIV test. Those aged 25–30 years were meanwhile found to be first-time testers 46 percent of the time, and those aged 31 and over were first-time testers 38 percent of the time. After an adjustment for region and sex, young adults had 2.84 (2.07, 3.90) increased odds of being a first-time tester when compared to participants 31 years and older.

Table 2 First-time testers: Young adults and males

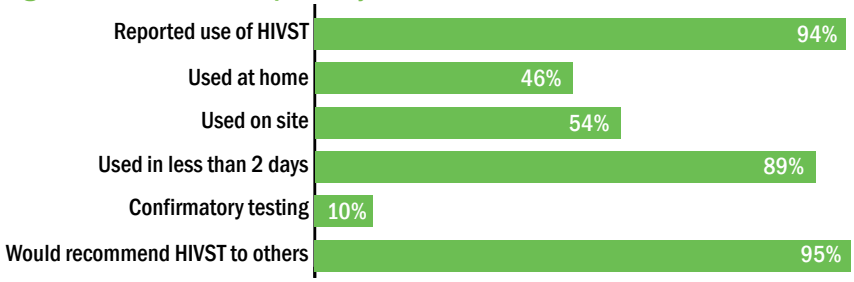
Characteristics	Total		HIV testing history								
			First time tester		Individuals with testing history		X^2 p-value	OR	aOR*	95% CI	p-value
	n/N	%	n/N	%	n/N	%					
Age							<0.001				
18–24	286/1130	25	179/285	63	106/285	37		2.75	2.84	2.07,3.90	<0.001
25–30	370/1130	33	169/367	46	198/367	54		1.39	1.32	1.00,1.76	0.063
31+	474/1130	42	171/444	38	293/473	62		Ref	Ref		
Sex at birth							<0.001				
Female	607/1148	53	233/604	39	371/604	61		Ref	Ref		
Male	541/1148	47	303/539	56	236/539	44		2.04	2.71	2.08,3.52	<0.001

*Adjusted for region and sex

Follow-up results: Post-test survey results

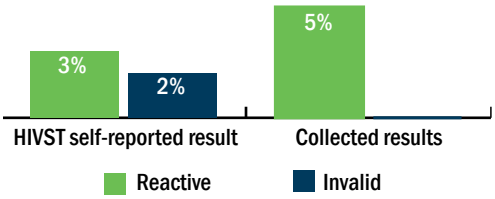
Among the 817 individuals who participated in the post-test survey two weeks post-distribution, 94 percent reported having used the HIVST kit. Fifty-four percent of participants chose to use the test at the distribution site while 46 percent used it at home. Eighty-nine percent of participants reported that they had used the self-test kit within two days of the distribution date, but only 10 percent of individuals reported having sought confirmatory testing. A vast majority of participants, 95 percent, reported that they would recommend the HIVST kit to others. Overall, we found that use and acceptability of HIVST did not significantly differ between first-time testers and those with a previous testing history.

Figure 4 Use and acceptability of HIVST



The study then analyzed the reactivity of HIVST test results (Figure 5). Among post-test survey participants that self-reported their at-home test results, 3 percent reported a reactive, or positive, result. Meanwhile, 2 percent reported having received an invalid result. Among tests that were self-administered at the distribution sites rather than at home, 5 percent of results were reactive.

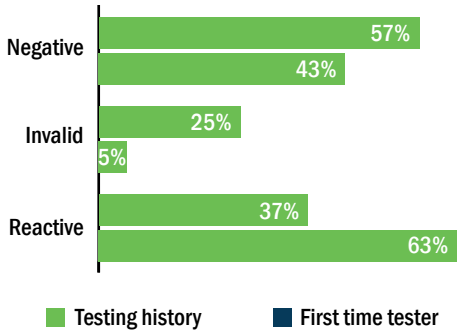
Figure 5 HIV results among study participants



Among participants that self-reported a reactive result, 63 percent were first-time testers and 37 percent had a previous testing history. Those that obtained invalid results were first-time testers 75 percent of the time and had a testing history 25 percent of the time. Meanwhile, from among those with negative test results, 57 percent had a testing history while 43 percent did not. Overall, the HIVST results were found to be statistically significantly associated with participants' previous testing history.

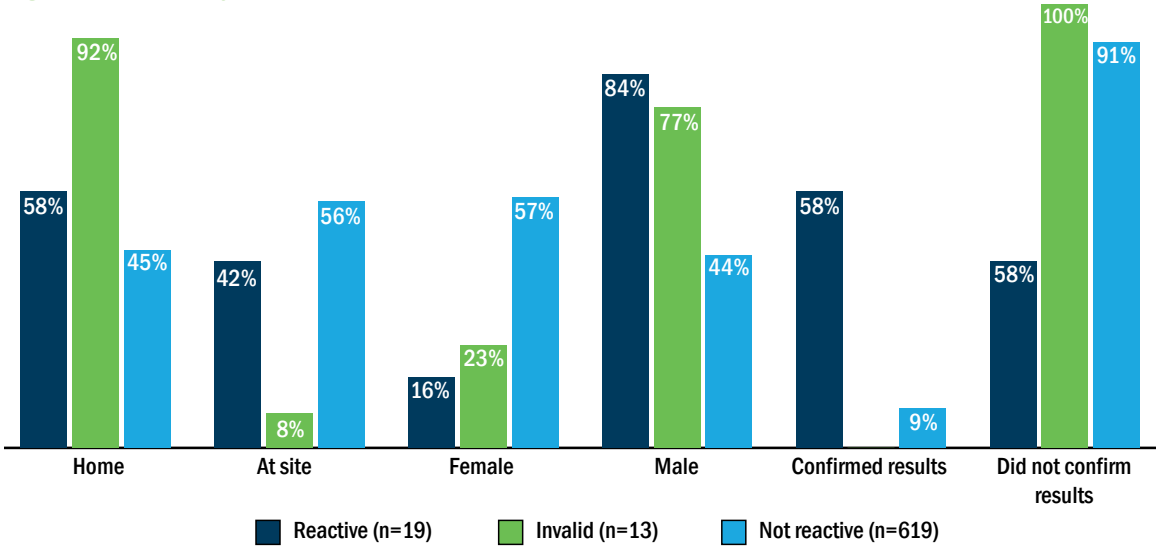
We further analyzed HIVST reactivity results by place of test use, participant sex at birth, and presence or lack of confirmatory testing. Among participants with invalid, or undetermined results, 92 percent self-administered the tests at home. This indicates that there may be some incorrect use or reading of the HIVST among those that administered at home. If these were to be used at home more widely, we would consider providing additional information or guidance for those self-administering.

Figure 6 Self-reported results and HIV testing history



We described earlier that 10 percent of all participants surveyed using the post-test sought confirmatory testing after their self-administered HIVST. Among participants with reactive results, 42 percent did not seek confirmation of their results. Meanwhile, among participants with an invalid result, none confirmed their results.

Figure 7 Reactivity of HIVST



Discussion

The results show that HIVST can effectively engage those that have never previously received HIV testing, first-time testers, in Senegal. This includes key populations like sex workers, men who have sex with men, injectable drug users, and trans women, as well as men and young adults who are often not reached by traditional testing programs.

Approximately half of MSW, MSM, PWID, and transgender women reached through HIVST reported not having previously tested for HIV. Few programs currently exist to provide tailored health services to PWID and transgender women in Senegal, and this study suggests that HIVST may provide an opportunity for PWID and transgender women to increase uptake of testing in this context.

The emergence of social media and technology to engage young adults through social and sexual networks may provide an avenue for increasing uptake of HIV testing services for these populations (Perrin 2015). Mobile phone apps have also been shown to be acceptable among young MSM in other settings and have been used to assess risk and coordinate HIVST distribution (Sullivan & Driggers 2017; De Boni et al. 2017; Smith et al. 2017). HIVST web-based delivery has been acceptable across settings, including sub-Saharan Africa, and may provide further opportunity to increase uptake and frequency of testing among young MSM (Sullivan & Driggers 2017; De Boni et al. 2017; Smith et al. 2017). Mobile technology may also be an opportunity to reach individuals in rural areas where program coverage and access to services is less, such as the region of Ziguinchor (Sullivan, Grey & Rosser 2013).

Expanding access to HIVST may increase the coverage and frequency of HIV testing among key populations, and could thus have a role in linking PLHIV to diagnosis and treatment services, potentially helping to mitigate the HIV epidemic in Senegal. Connecting HIVST with confirmatory testing and linkage to care was a challenge during the implementation of this study. HIVST

strategies in Senegal may require more active mechanisms for follow-up and support in order to improve the pipeline from self-testing to confirmatory testing and care.

This small-scale implementation highlights the importance of leveraging existing structures and programs for distribution. However, adoption and integration of HIVST into existing programs will require a revision of the current HIV testing targets for programs in Senegal. HIVST indicators have been incorporated into the PEPFAR Monitoring, Evaluation, and Reporting (MER 2.0) Indicator Reference Guide representing appropriate indicators for collection in HIV testing programs (PEPFAR 2017). Notably, the HIV testing yield for programs may decrease if HIVST are included, though there will be a lower cost per test offered (Cambiano et al. 2015). Sustained engagement with the Senegalese government and other stakeholders will be needed in order to strategize the implementation and scale-up of HIV self-testing in Senegal.

AIMS 2 AND 3: CASE MANAGEMENT VS. STANDARD OF CARE

Overview

This study assessed the Senegalese SOC and CM in order to compare the effectiveness and durability in achieving SVS among PLHIV in Senegal. The SOC for treatment support for PLHIV in Senegal included facility-based ART initiation and follow-up systems leveraging appointment books without active reminders. All arms of the study, including SOC, included referrals for ART irrespective of CD4 counts for people who arrived at the test clinics—i.e., “test and treat.”

Methods

The CM intervention was a multi-step process to coordinate care and provide a family-like support system for PLHIV. Peer health navigators received a capacity building training in case management at each study site as part of the intervention. The training's goal was to reinforce their health navigation capacities, train them in case management, and provide them with the tools to adequately fulfill their role as new case managers.

After assignment of a case manager, the approach had five key components: 1) initial meeting between person living with HIV and case manager; 2) follow-up meeting between case manager and participant; 3) biweekly automatic text messages sent to participant; 4) monthly phone calls from case manager; and 5) face-to-face meetings between case manager and participant every six months. Each component is outlined below:

1. The initial meeting between person living with HIV and case manager to establish expectations and reflect upon treatment goals.
2. Following this initial meeting, the case manager and participant meet again within two weeks to finalize goals and to focus on skills and self-efficacy building to achieve treatment goals. During this visit, the person living with HIV determines if he/she wants to receive the standard level of text messages and calls or if he/she desires additional interaction.
3. Automated text messages are sent every two weeks to provide support and further promote self-efficacy (e.g., tips for remembering to take treatment, nutritional advice, condom

negotiation, and information about signs of co-infections). The content of the SMS was finalized based on consultations with multiple stakeholders to ensure that they are effective yet confidential. We consider the SMS as a core component of the interventions.

4. Monthly phone calls from the case manager to review treatment goals, adherence performance and challenges, and logistics support; participants may also call the case manager anytime during the month or place a free "Please Call Me," which is returned as soon as possible by the case manager.
5. Every three months following the initial sessions, the case manager will meet face-to-face with the participant and comprehensively evaluate achievement of goals and set new goals going forward. Clinic appointment reminders will also be sent to participants, both 7 days and 24 hours prior to follow-up, and participants will be triggered with a phone call by the case manager if the appointment was unexpectedly missed.

Sample size

The total proposed sample size for the randomized controlled trial for case management across both cities was 596 participants.

To estimate the sample size for this study, we assumed a cumulative 20 percent loss to follow-up at the end of the study period. We assumed this loss to follow-up to be distributed equally across each 3-month study visit, resulting in a total sample size required for randomization of 596 PLHIV who are not virally suppressed. The sample size calculation was computed under the assumption that annual viral suppression rate is as high as 60 percent under SOC, and would increase to a minimum of 80 percent among those receiving the CM intervention. Thus, with a sample size of 596 with 298 in each of the two cities with study sites, we would have 90 percent power at 5 percent level to detect a difference of at least 20 percent between the control and intervention. The two sites have been powered independently and pooling of data only takes place if there is sufficient homogeneity of results.

Table 3 Sample calculation size table

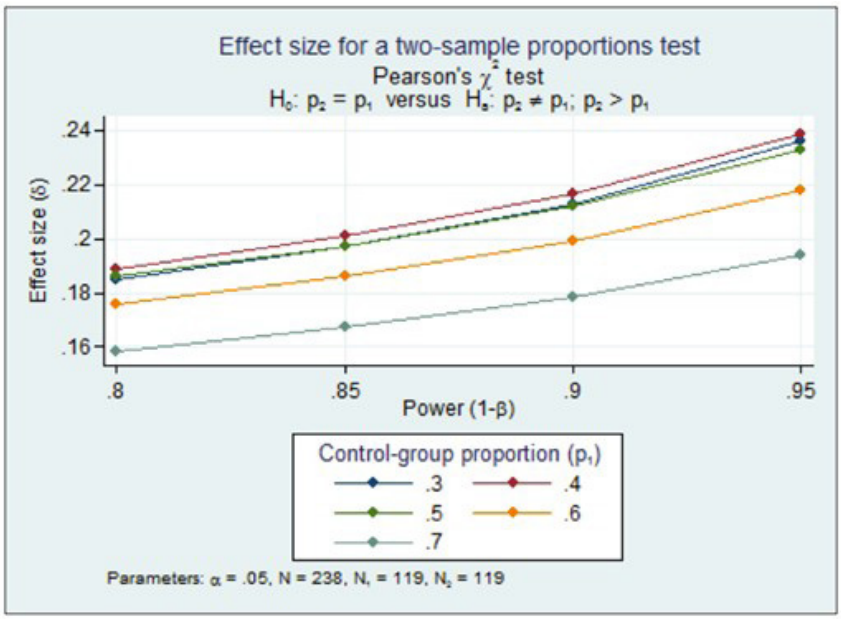
Alpha	Power	N	N1	N2	Delta	p1	p2
0.05	80%	238	119	119	18%	30%	48%
0.05	90%	238	119	119	21%	30%	51%
0.05	80%	238	119	119	19%	40%	59%
0.05	90%	238	119	119	22%	40%	62%
0.05	80%	238	119	119	19%	50%	69%
0.05	90%	238	119	119	21%	50%	71%
0.05	80%	238	119	119	18%	60%	78%
0.05	90%	238	119	119	20%	60%	80%

Notes: N=Total sample size by site/city, N1/N2= Standard of care/Intervention sample size, p1 = Annual viral suppression rate under standard of care, p2= Viral suppression rate under the proposed intervention

Effect size estimates for a two sample proportions test is shown in Figure 8. This figure illustrates the magnitude of effect needed to observe a significant difference ($p<0.05$) between the control and intervention groups. The control group proportion is representative of the 12-month viral

suppression rate among those living with HIV from SOC. The range of assumptions is from 30 to 70 percent viral suppression (VS) at 12 months with a conservative estimate that 60 percent are VS at that time point. The Y-axis refers to the effect size of the intervention with ranges from 16 to 24 percent effect and then X-axis referring to the power from 80 to 95 percent power. With a conservative estimate of 20 percent effectiveness in SVS as compared to SOC and a baseline VS of 12 months of 60 percent, we will have 90 percent power and type-1 (alpha) error of 5 percent with a sample size of 119 in each study arm in each study site. Thus, we require 238 per study site, and with an assumed annual loss to follow-up of 20 percent, we require 298 per city or a total of 596 participants across two clinics in Dakar and one clinic in Ziguinchor.

Figure 8 Effect size



The total sample size for the RCT study across both cities was 596.

Participants and recruitment

The study population for the CM vs. SOC intervention of this study is PLHIV who are not virally suppressed, and are included independent of their CD4 count. Eligible participants were 18 years of age or older at the time of enrollment into the study. All study participants must also be residents of Senegal for at least three months and plan to reside in Dakar or Ziguinchor for at least the next year. We assessed acquisition and transmission risk factors among the PLHIV included in our study but individuals were not be included or excluded based on behavioral risk factors. Thus, while this study didn't specifically limit inclusion to MSM or FSWs, there was an expectation that a significant proportion of people diagnosed with HIV in Senegal are members of these groups or other key populations, and ensuring sensitive services was crucial.

Inclusion criteria

- 18 years of age or older
- Mentally sound and capable of providing consent to participate
- Agrees to complete HIV and syphilis testing
- Speaks either French, Wolof or both
- Provided informed consent to participate in the study
- Resident of Senegal for the past 3 months
- Intention to live in Dakar or Ziguinchor for the next 12 months
- Agrees to complete all required biological testing described in the consent form and receive results

Exclusion criteria

- Under 18 years of age
- Demonstrates mental incapacity, under the influence of substances, or any other illness preventing comprehension of the study procedures and informed consent
- Does not agree to complete all required biological testing described in the consent form or receive results
- Has not provided informed consent to participate in the study

Recruitment process

Recruitment and participant enrollment into the RCT took place at the health facility assigned as a study site. Self-testing kits were used as a means to increase the number of potential study participants visiting the designated health facilities and facilitate recruitment into the study. However, study participants were not excluded if not recruited through the self-testing kits.

Participants who visited the study sites and tested positive for HIV were assessed for eligibility into the study. Trained health facility staff provided potential study participants with information about the study in broad terms. The initial information provided included the target population of the study, as well as the overall objective of the study. The potential participant was then referred to study staff within the study site, if they chose to be assessed for eligibility and enrollment.

The work of informing and ultimately consenting participants was done by the study staff, who were the same staff members that worked on this study throughout. Throughout the consent and discussions, the study team emphasized that participation was voluntary and would not impact their involvement with the health facility, and that engaging in the study would have no bearing on their level of service from health facility.

Once the participant was determined to be eligible, they were enrolled into the study by trained study staff.

Consent process

Laboratory technicians, nurses, or quantitative interviewers obtained informed consent from participants. All study staff members with direct contact with study participants were certified in CITI ethics training or other comparable training programs, completed an in-person ethics training conducted by the study investigators, and were supervised by the local PI to ensure adherence to study protocol and consent requirements, ethical and confidential practices with participants, and data management.

All consent discussions occurred at the study site. The consent form was reviewed and an opportunity for participants to ask questions was provided. Informed consent was provided by participants who met the eligibility criteria prior to the beginning of any research activities with the participant. If eligible, the participant was informed about the cohort. At this point, participants were required to provide a phone number and/or email address for the study staff to use for appointment reminders. Participants were informed of the process, and that call history and numbers would be deleted after a call has been made. Using a consent script approved by JHSPH IRB and the local IRB, the study staff explained the study, outlining the purpose, sequence of events, rights, and potential risks and benefits to participants. Other aspects of the consent process were identical to the baseline assessment, but the consent script was different from the consent script of the baseline assessment. Participants were offered a copy of the consent form but were not required to take it.

We documented if a potential participant declined to participate during the consent process. The reason for not participating was recorded by the interviewer. Additionally, if a participant retracted their consent at any point throughout the study, the reason for this retraction was documented by the interviewer.

The interviewer asked the participant a series of eligibility questions to assess whether he or she met the criteria. We obtained signatures from participants rather than using oral consent per requirements from the Senegalese ethics committee.

Adults lacking capacity to consent were ineligible to participate in the study, therefore we did not obtain a legally authorized representative's signature. To protect participants' privacy, we did not include a witness to the consent process.

Study implementation and data collection

Peer health navigators received a capacity building training in case management at each study site as part of the intervention. The training's goal was to reinforce their health navigation capacities, train them in case management, and provide them with the tools to adequately fulfill their role as new case managers.

Eligible participants recruited through the study site health facilities went through the consent process in private rooms within the project office and completed a structured 1-hour interviewer-administered questionnaire, which served as the baseline assessment. Participants were enrolled into the study by trained study staff at a study site.

Participants assigned to the CM intervention received Standard of Care treatment, and were provided CM support. After assignment of a case manager, the CM approach had five key components:

1. The initial meeting between person living with HIV and case manager to establish expectations and reflect upon treatment goals.
2. Following this initial meeting, the case manager and participant met again within two weeks to finalize goals and to focus on skills and self-efficacy building to achieve treatment goals. During this visit, the person living with HIV determined if he/she wanted to receive the standard level of text messages and calls or if he/she desired additional interaction.
3. Automated text messages were sent every two weeks to provide support and further promote self-efficacy (e.g., tips for remembering to take treatment, nutritional advice, condom negotiation, and information about signs of co-infections). The content of the SMS was developed based on consultations with multiple stakeholders to ensure that they were effective yet confidential.
4. Monthly phone calls from the case manager reviewed treatment goals, adherence performance and challenges, and logistics support; participants could also call the case manager anytime during the month or place a free "Please Call Me," which was returned as soon as possible by the case manager.
5. Every three months following the initial sessions, the case manager met face-to-face with the participant and comprehensively evaluated achievement of goals and set new goals going forward. Clinic appointment reminders were also sent to participants, both 7 days and 24 hours prior to follow-up, and participants were triggered with a phone call by the case manager if the appointment was unexpectedly missed.

Case managers filled out a case manager form at each visit with each study participant. The aim of this data collection was to understand the implementation of the intervention from the perspective of the case managers. Case managers conducted visits with participants to provide supportive services, assess barriers to ART, and provide referrals. Therefore, the case managers provided information for the purpose of the study on the visit and their assessment with the participants. The information included barriers to participants' adherence to ART and referrals provided to the participant. These forms were collected from the case managers for each participant visit.

All study visits took place at the study site representing an existing health facility in either Dakar or Ziguinchor. Each study visit lasted approximately two hours.

Table 4 Study visits

Visit	Month	Biological testing	Questionnaire	Max duration
1 (Baseline)	0	Yes	Full assessment	2 hours
2	3	No	Abbreviated	1 hour
3	6	Yes	Full assessment	2 hours
4	9	No	Abbreviated	1 hour
5	12	Yes	Full assessment	2 hours

Baseline assessment of study participants included a questionnaire and biological testing. The baseline questionnaire assessed demographic characteristics, socioeconomic status, mobility and migration history, behavioral characteristics, health and HIV treatment history, and HIV acquisition risks. The baseline assessment also collected information on HIV testing history, specifically recent use of HIVST. For those who received an HIVST kit, there was significant attention on the measurement of implementation outcomes including the use of HIVST, HIVST results, acceptability, routinization, feasibility, and adoption.

Follow-up involved visits at 3, 6, 9, and 12 months after the first visit. Questionnaires were administered at each visit. Questionnaires assessing behavioral characteristics, mental health, social support, and ART treatment adherence were administered at 6 months and 12 months.

Abbreviated questionnaires were re-administered at three and nine months though no biological assessments were completed at these time points. The questionnaires leveraged existing instruments that have detailed assessments of implementation outcomes associated with HIVST; the use of iris for tracking and engagement in ART services; and enacted, perceived, and intersectional stigma. In addition, we used implementation indicators that explore measures of acceptability, fidelity, appropriateness, and routinization of the CM intervention.

Cost effectiveness of the CM approach

The data needed to later complete cost-effectiveness assessments of the use of CM intervention were collected as part of this study. From the participant perspective, we used a standardized questionnaire based on the WHO's "Tool to Estimate Patients' Costs" to assess the cost to individuals in accessing and maintaining participation in CM. Participant costs include: (a) lost wages and productivity required to attend the CM visits; (b) transportation and ancillary costs (e.g., food, childcare) necessary for attendance; (c) internet and cell phone use charges; and (d) costs associated with behavior change itself (e.g., cost of acquiring condoms and HIV tests, lost wages due to foregone risky sexual encounters). We also used two instruments: the brief version of the WHO Quality of Life instrument (WHOQOL-BREF[5]) and the EQ-5D[6] to assess participants' quality of life and health utility, respectively. The WHOQOL-BREF is a 26-item instrument that measures quality of life across four broad domains: physical health, psychological health, social relationships, and environment; the EQ-5D is a five-item survey that can provide estimates of health utility (score from 0 = death to 1 = perfect health). The use of these two instruments enabled us to capture not only the indirect effects of such interventions on reducing HIV transmission, but also their direct effects on individuals' quality of life.

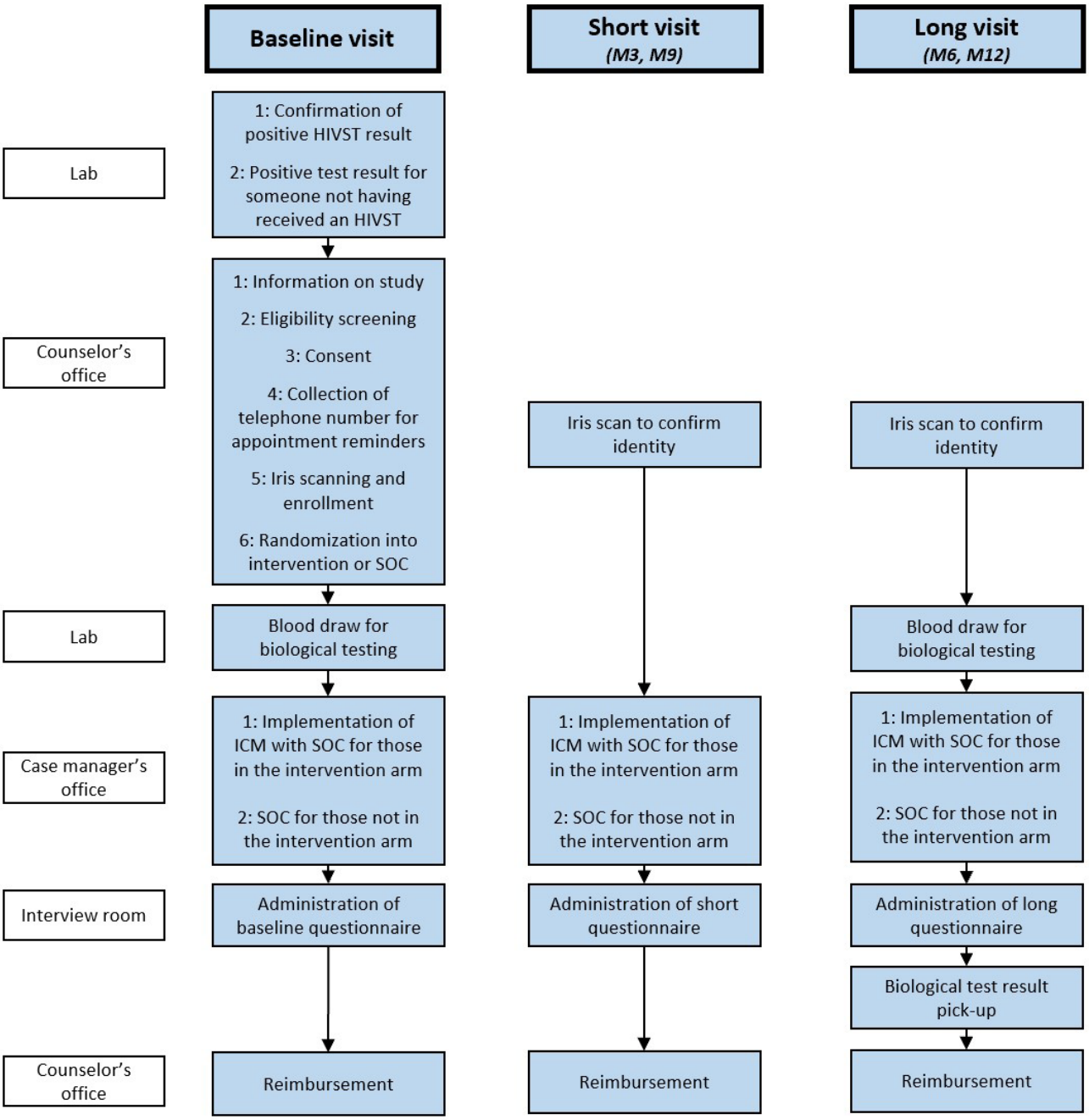
Cost-related data were collected from the healthcare perspective as well. These costs included (though were not limited to): (a) hiring and training of case managers; (b) monthly costs of preparing and delivering support through case managers; and (d) program implementation and oversight, including physical resources (e.g., office space), human resources, and overhead. Time requirements for each activity were measured by direct observation using time-motion studies; additional budgetary requirements were elicited through structured discussions with staff

[5]https://www.who.int/tools/whoqol/whoqol-bref

[6]https://euroqol.org/eq-5d-instruments/

members and case managers. (However, no personal information was collected from staff or case managers).

Figure 9 Site flow



The study lasted 15 months from the time of the first participant enrollment to the last study visit. Each participant was part of the study for a maximum of 12 months. The cohort follow-up involved five study visits, lasting up to two hours each. Participants also had the opportunity for clinical visits and intervention activities, but these will vary by person and are separate from study visits.

Measures were taken to ensure personal information of the study participants was protected during data collection and data storage.

Data analysis

Effectiveness and durability of the CM approach

We estimated the effectiveness and durability of CM vs. SOC interventions focused on achieving SVS to inform the SOC. The primary effectiveness outcomes were SVS defined using quantitative viral load assessment with <400 copies/ml at 12 months after initial randomization. To compare the effectiveness and durability of CM programs vs. SOC to achieve SVS, we conducted a difference of proportions Intention to Treat (ITT) analysis comparing SVS at 12 months between participants randomized to CM vs. SOC. Interim analyses at 6 months of differences in viral suppression were also completed. Secondary outcomes include: 1) durability of viral load suppression among 6-month responders continuing CM vs. those randomized to SOC.; 2) loss-to-follow-up across arms; and 3) participant reported implementation outcomes including acceptability and routinization of the intervention. Loss to follow-up was compared across study intervention arms using GEE models with a binomial distribution and logit function and accounting for baseline characteristics using inverse probability treatment weights (this is necessary for this non-ITT analysis as people were re-randomized to new arms over time and thus benefits of randomization are lost). Uptake, acceptability, and intervention fidelity are described. Missing data were handled using multiple imputation if missing was at random and more than 5 percent.

Cost-effectiveness of the CM approach

To determine the cost-effectiveness of the universal treatment approach using the CM intervention, we performed a comprehensive costing of our study intervention, from the perspectives of both the healthcare system and the participants. Our costing methodology followed World Health Organization (WHO) recommendations for cost-effectiveness analysis, with estimates of unit costs compared against WHO's CHOosing Interventions that are Cost-Effective (CHOICE) global estimates for countries in Senegal's region.

Results

Participants demographic characteristics

The sample included 573 participants that were allocated to receive either standard of care (n=281) or the case management treatment (n=292). The two groups were compared based on characteristics such as age, education, employment status, marital status, living situation, sex and gender, city, key population status, and treatment status.

The demographic breakdown of the two study arms, detailed in Table 5, show that randomization was successful given the similarity in characteristics. On average, participants were 36 years of age and the largest proportion (35%) had never attended school. Forty-two percent of the participants were unemployed while 24 percent were independent workers and 6 percent were students. Most participants were either married (44%) or single/never married (34%) while 14

percent were widowed. Most participants, 63 percent, indicated that they lived with family. Fifty-six percent of participants indicated that their sex at birth was female, and 57 percent identified as female at the time of the intervention.

Among the SOC group, 21 percent of participants were sex workers while 24 percent were MSM. The proportion of these key populations was slightly smaller among the CM group, where 16 percent of participants were sex workers and 21 percent were MSM. Forty-three percent of SOC participants were on treatment at the outset of the intervention while a majority, 89 percent, had been newly diagnosed with HIV. In the CM group 46 percent were on treatment and 85 percent were newly diagnosed.

Table 5 Baseline demographic characteristics among participants in study arms

	Standard of care n (%)	Case management n (%)	Total n (%)	p-value
Age in years, mean (Interquartile range)	36 (28-46)	36 (27-47)	36 (28-46)	0.7837
Education				
Never went to school	93 (33)	106 (36)	199 (35)	
Incomplete primary school	48 (17)	45 (15)	93 (16)	
Primary school complete	41 (15)	31 (11)	72 (13)	
Incomplete secondary school	51 (18)	49 (17)	100 (18)	
Complete secondary school	13 (5)	17 (6)	30 (5)	
Professional training	10 (4)	9 (3)	19 (3)	
University studies	14 (5)	19 (7)	33 (6)	
Other	11 (4)	15 (5)	26 (5)	
Refusal	0 (0)	1 (0.3)	1 (0.2)	0.744
Employment status				
Unemployed	113 (40)	129 (44)	242 (42)	
Retired	3 (1)	2 (1)	5 (1)	
Training/student	17 (6)	14 (5)	31 (5)	
Temporary work	2 (1)	0 (0)	2 (0.3)	
Independent worker	70 (25)	66 (23)	136 (24)	
Salaried (short-term contract)	12 (4)	10 (3)	22 (4)	
Salaried (long-term contract)	8 (3)	11 (4)	19 (3)	
Other	56 (20)	60 (21)	116 (20)	0.751
Marital status				
Married	115 (41)	136 (47)	251 (44)	
Single/never married	96 (34)	97 (33)	193 (34)	
Divorced/separated	28 (10)	17 (6)	45 (8)	
Widowed	41 (15)	41 (14)	82 (14)	
In a relationship	1 (0.4)	1 (0.3)	2 (0.3)	0.374
Living situation				
With family	179 (64)	180 (62)	359 (63)	
With friends	9 (3)	2 (1)	11 (2)	
Renting a place	69 (25)	72 (25)	141 (25)	
Own a place	10 (4)	22 (8)	32 (6)	
Dormitory	1 (0.4)	0 (0)	1 (0.2)	
Other	13 (5)	16 (6)	29 (5)	0.072
Literacy				
No	134 (48)	143 (49)	277 (48)	
French	80 (29)	74 (25)	154 (27)	
Wolof	13 (5)	11 (4)	24 (4)	
French and Wolof	53 (19)	64 (22)	117 (20)	
Don't know	1 (0.4)	0 (0)	1 (0.2)	0.642
Sex at birth				
Male	130 (46)	125 (43)	255 (45)	
Female	151 (54)	167 (57)	318 (56)	0.405
Gender identify				
Male	108 (38)	97 (33)	205 (36)	
Female	155 (55)	174 (60)	329 (57)	
Other	16 (6)	20 (7)	36 (6)	
Refusal	1 (0.4)	0 (0)	1 (0.2)	
Don't know	1 (0.4)	1 (0.3)	2 (0.3)	0.571
Region				
Dakar	146 (67)	154 (65)	300 (66)	
Ziguinchor	73 (33)	84 (35)	157 (34)	0.659
Key populations				
Sex workers*	59 (21)	46 (16)	105 (18)	0.154
Men who have sex with men**	66 (24)	61 (21)	127 (22)	0.562
Treatment				
Newly diagnosed with HIV	249 (89)	249 (85)	498 (87)	0.236
On treatment	121 (43)	134 (46)	255 (45)	0.496

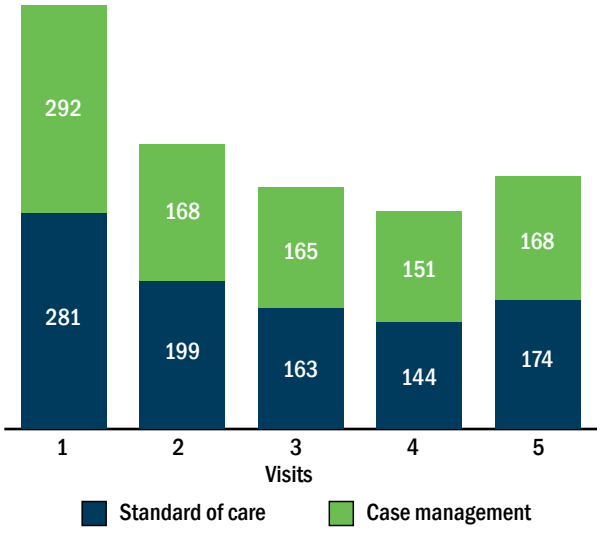
*Have you ever exchanged sex for money or goods?
**Have you ever had sex (anal or oral) with a male?

Cohort follow-up

Several avenues were targeted for the recruitment of study participants. The first lead was people newly screened through the HIV self-testing strategy that was deployed in all the study cities. The second lead was newly screened patients through the routine screening program at the study sites. The third option was to recruit newly screened and managed patients at the care sites who are referred to the study sites.

The first study visit was conducted at baseline (Visit 1), and was followed by four more visits at 3, 6, 9, and 12 months. Figure 10 shows the number of participants in the SOC and CM intervention arms participating in each study visit. At the first study visit, 289 CM and 278 SOC group members participated in the three different sites. Both numbers decreased significantly during the second visit, with 186 CM and 199 SOC participants. A smaller decrease was seen during the third study visit, with 141 participants from each of the two study arms, which was then followed by slight increases during the fourth and fifth visits. During the fifth and final visit, 168 CM and 174 SOC participants took part in the study.

Figure 10 Participation in study visits by study arm



There are several reasons for the lower number of participants in post-inclusion visits. First, there is the mobility of patients, especially key populations. Although the study criteria for participation required the individual to confirm that they would be staying in the study for at least the duration of the study, some patients moved to other parts of the country or sometimes even outside the country depending on their activities. In addition, the study period coincided with several moments of strike and protests by the health workers unions during which all activities were at a standstill at the various sites. Finally, there was the rain season during which a good part of the people in Casamance leave the cities to return to the remote villages and do not return until the end of the season. This is not specific to the study, but also impacts all follow-up of PLHIV in this region.

Disclosure and stigma

Participants shared experiences of disclosure and stigma attributable to HIV status and sexual behavior. Stigma from family and friends was measured as feeling excluded from family activities, feeling rejected by friends, and being spoken to in a negative manner. Stigma from healthcare workers was measured as feared or avoided seeking healthcare; felt mistreated, denied, or kept from health services; or felt spoken to negatively by a healthcare worker. Stigma from the community was measured as being afraid to be in public or having been verbally or physically harassed, blackmailed, or forced to have sex. Additionally, questions on fear of uniformed officers

were asked to participants who ever had sex in exchange for money or goods and/or had sex with men.

HIV-related stigma

Among the participants in the CM arm, 51 percent reported having shared their positive HIV status with a family member, and 28 percent in the SOC arm. Overall, a small proportion of participants reported having felt excluded by friends (3%) or from family activities (4%). In healthcare settings, only 9 percent participants shared having ever avoided seeking healthcare. No participant reported feeling mistreated or having been denied services by healthcare workers. Among the CM participants, 9 percent reported fear of being in public places and 2 percent of having been blackmailed, compared to 6 percent that were blackmailed in the SOC arm. No participant reported having ever been physically harassed or forced to have sex because of their positive HIV status in either study arm.

Table 6 Disclosure and HIV-related stigma among participants at baseline

	SOC (n=33) n (%)	CM (n=43) n (%)	Overall (n=76) n (%)	p-value
Told family member HIV status	9 (28)	22 (51)	31 (41)	0.045
Stigma from family and friends				
Felt excluded from family activities	2 (6)	1 (2)	3 (4)	0.391
Family member made a negative remark or gossiped	4 (13)	1 (2)	5 (7)	0.081
Felt rejected by friends	2 (6)	0 (0)	2 (3)	0.177
Healthcare				
Feared seeking healthcare	2 (6)	4 (9)	6 (8)	0.630
Avoided seeking healthcare	2 (6)	5 (12)	7 (9)	0.382
Felt mistreated in a healthcare center	0 (0)	0 (0)	0 (0)	
Denied or kept from health services	0 (0)	0 (0)	0 (0)	
Felt healthcare worker made negative remarks or gossiped	0 (0)	0 (0)	0 (0)	.
Community				
Afraid to be in public places	0 (0)	4 (9)	4 (5)	0.076
Verbally harassed	1 (3)	1 (2)	2 (3)	0.832
Blackmailed	2 (6)	1 (2)	3 (4)	0.391
Physically harassed	0 (0)	0 (0)	0 (0)	

Sexual behavior-related stigma

MSM are often stigmatized by their social environment, family, or friends. This often leads to their exclusion or rejection because of their behavior or sexual orientation. In this study, the results show that out of 112 MSM surveyed at baseline, only nine felt comfortable enough to talk about their sexual orientation with their family or friends. Sixteen percent (n=18) have at least once been the victim of negative remarks from a family member about their sexual orientation. These remarks often lead to the exclusion of the from family activities (9%, n=10). These negative comments and/or exclusion from family activities were more prevalent among those in the standard care arm (19% and 16%) than those in the case management arm (2% and 13%).

A few MSM participants, 14 percent (n=16), were often afraid to attend health facilities for their care needs, due to their perceived risk of stigmatization. This was more common among patients followed in standard care (19%) than those followed in case management (9%). However, the results of the study showed that it is rare for patients to be mistreated in a health facility because they are MSM—1 percent (n=1) reported this; or to be stigmatized by health providers, with 3 percent (n=3) reporting this.

MSM reported experiencing stigma from the police. Eight MSM, or 7 percent, reported having been arrested by the police; five or 4 percent, had been harassed by the police; and three or 3 percent, had been refused protection by the police because of their sexual orientation.

Social stigma is common among MSM. Indeed, nine MSM, or 8 percent, said they were afraid to go to public places at least once because of their sexual orientation. They were often victims of verbal harassment (13%), physical harassment (12%), or blackmail (13%).

Table 7 Disclosure, sexual behavior-related stigma among MSM at baseline

	SOC (n=58) n (%)	CM (n=55) n (%)	Total (n=112) n (%)	p-value
Told a family member sexual behavior	6 (10)	3 (6)	9 (8)	0.337
Family and friends				
Felt excluded from family activities	9 (16)	1 (2)	10 (9)	0.015
Family member made a negative remark or gossiped	11 (19)	7 (13)	18 (16)	0.244
Felt rejected by friends	8 (14)	1 (2)	9 (8)	0.063
Healthcare				
Feared seeking healthcare	11 (19)	5 (9)	16 (14)	0.132
Avoided seeking healthcare	8 (14)	4 (7)	12 (11)	0.261
Felt mistreated in a healthcare center	1 (2)	0 (0)	1 (1)	0.328
Denied or kept from health services	0 (0)	0 (0)	0 (0)	
Felt healthcare worker made negative remarks or gossiped	2 (3)	1 (2)	3 (3)	0.590
Uniformed officer				
Felt not protected by uniformed officer	3 (5)	0 (0)	3 (3)	0.087
Avoided carrying condoms	6 (10)	3 (6)	9 (8)	0.337
Condoms confiscated or destroyed	0 (0)	1 (2)	1 (1)	0.302
Felt harassed or intimated	4 (7)	1 (2)	5 (4)	0.189
Arrested on charges related to homosexuality	6 (10)	2 (4)	8 (7.)	0.165
Community				
Afraid to be in public places	3 (5)	6 (11)	9 (8)	0.260
Verbally harassed	10 (17)	5 (9)	15 (13)	0.202
Blackmailed	12 (21)	3 (6)	15 (13)	0.017
Physically harassed	10 (17)	3 (6)	13 (12)	0.050
Forced to have sex	19 (33)	8 (15)	27 (24)	0.023

Like MSM, many of the SW surveyed were also stigmatized because of their sexual behaviors and practices. This stigmatization generally comes from their social environment, family, or friends. In

this study, the results show that out of 33 interviewed SW, only five (15%) felt comfortable enough to talk to a family member about their situation, four SW (12%) were victims of negative remarks by a family member because of their activities or behavior, and three (9%) said they were rejected by their friends for reasons related to their sex work.

As among MSM, the percentage of SW who reported perceiving stigma in the medical setting was low. No SW participant reported being afraid to go to health facilities because of their profession.

A minority of SW reported having been stigmatized by the police. Two (6%) said they lacked police protection. Three (9%) were victims of police harassment, and 6 (18%) were victims of arrest by the police in the course of their work.

Social stigma is the phenomenon most felt among SW in this study. In addition to stigmatization, FSWs also reported being survivors of violence. This violence can take the form of physical assault (15%), fear of going to public places (9%), verbal harassment (12%), blackmail (18%), or assault or sexual violence (24%).

Table 8 Disclosure and sex work-related stigma among sex workers at baseline

	SOC (n=22)	CM (n=11)	Total (n=33)	p-value
	n (%)	n (%)	n (%)	
Told a family member sexual behavior	4 (18)	1 (9)	5 (15)	0.492
Family and friends				
Felt excluded from family activities	3 (14)	0 (0)	3 (9)	0.199
Family member made a negative remark or gossiped	4 (18)	0 (0)	4 (12)	0.131
Felt rejected by friends	3 (14)	0 (0)	3 (9)	0.199
Healthcare				
Feared seeking healthcare	0 (0)	0 (0)	0 (0)	
Avoided seeking healthcare	0 (0)	0 (0)	0 (0)	
Felt mistreated in a healthcare center	0 (0)	0 (0)	0 (0)	
Denied or kept from health services	0 (0)	0 (0)	0 (0)	
Felt healthcare worker made negative remarks or gossiped	0 (0)	0 (0)	0 (0)	
Uniformed officers				
Felt not protected by uniformed officer	2 (9)	0 (0)	2 (6)	0.302
Avoided carrying condoms	3 (14)	0 (0)	3 (9)	0.199
Condoms confiscated or destroyed	2 (9)	0 (0)	2 (6)	0.302
Felt harassed or intimidated	2 (9)	1 (9)	3 (9)	1.000
Arrested on charges related to prostitution	3 (14)	3 (27)	6 (18)	0.338
Community				
Afraid to be in public places	2 (9)	1 (9)	3 ()	1.000
Verbally harassed	4 (18)	0 (0)	4 (12)	0.131
Blackmailed	5 (23)	1 (9)	6 (18)	0.338
Physically harassed	4 (18)	1 (9)	5 (15)	0.492
Forced to have sex	5 (23)	3 (27)	8 (24)	0.774

Condom use

During the first, third, and fifth visits, participants received full assessments through questionnaires, including questions aiming to measure behavioral characteristics such as condom use. Table 9 shows the condom usage results from these three visits for both the SOC and CM treatment arms.

Participants were asked to indicate how often they used a condom for sex with their principal partners over the past 30 days. The percentage of SOC participants indicating they had never used one decreased from 33 percent to 16 percent between the baseline and fifth visit. In the CM group, meanwhile, 28 percent initially indicated they had never used a condom with their principal partners over the past 30 days. This number decreased to 10 percent on the third visit and increased to 13 percent during the fifth visit. The proportion of participants that indicated they had used a condom with their principal partners rarely, from time to time, or often remained below 5 percent for all treatment arms and visits. The proportion of SOC participants indicating that they had always used a condom with their principal partners over the last 30 days increased from 10 percent to 20 percent between the first and last visit. The CM group, meanwhile, reported an increase from 11 percent to 21 percent between the first and third visits, and then decreased to 19 percent in the final visit.

Participants were also asked how often over the past 30 days they had used a condom for sex with their casual partners. Among the SOC arm, 24 percent of participants initially reported never having used a condom. This proportion decreased to 8 percent during the third visit and to 7 percent during the fifth visit. The CM arm saw an initial decrease from 25 percent during the first visit to 4 percent during the third visit. However, the number increased to 9 percent during the fifth visit. Similarly, the proportion of CM participants indicating they had always used a condom increased from 8 percent during the baseline visit to 18 percent during the third visit, and ultimately decreased to 16 percent during the fifth visit. Among SOC participants, 11 percent initially indicated always using a condom with their casual partners. This figure increased to 19 percent during the third visit and decreased to 15 percent during the fifth visit. In the case of condom usage for sex with casual partners, less than 3 percent of participants indicated using a condom rarely, from time to time, or often for all treatment arms and visits

Mental health

Mental health was assessed using the Patient Health Questionnaire (PHQ-9). A score of 0–4 suggests minimal or no depression, 5–9 mild depression, 10–14 moderate depression, 15–19 moderately severe depression, and 20–27 severe depression.

Table 10 illustrates the presence and severity of depression at the first, third, and fifth visit. Overall, the severity of depression decreased at all levels in both the SOC and CM arm.

Between the first and fifth visit, the percentage of participants in the SOC arm with no depression increased from 64 percent to 87 percent. This trend persisted as the proportion of participants experiencing mild depression decreased from 24 percent to 11 percent. Similarly, those experiencing moderate levels of depression decreased from 9 percent to 0.6 percent during the third visit, but increased to 2 percent during the fifth visit.

Table 9 Condom use among participants in study arms—12-month follow up

Over the past 30 days	Visit 1			Visit 3			Visit 5		
	SOC (n=281) n (%)	CM (n=292) n (%)	p-value	SOC (n=163) n (%)	CM (n=165) n (%)	p-value	SOC (n=174) n (%)	CM (n=168) n (%)	p-value
Condom use with principal partners									
Never	93 (33)	83 (28)		22 (14)	16 (10)		28 (16)	21 (13)	
Rarely	9 (3)	6 (2)		4 (3)	4 (2)		5 (3)	5 (3)	
From time to time	9 (3)	13 (5)		5 (3)	2 (1)		5 (3)	7 (4)	
Often	10 (4)	11 (4)		1 (0.6)	4 (2)		2 (1)	3 (2)	
Always	27 (10)	31 (11)		36 (22.	35 (21)		35 (20)	31 (19)	
Has not had sex	132 (47)	148 (51)		94 (58)	102 (62)		98 (56)	101 (60)	
Refusal	1 (0.4)	0 (0)	0.687	0 (0)	2 (1)	0.392	1 (0.6)	0 (0)	0.843
Condom use with casual partners									
Never	68 (24)	72 (25)		13 (8)	7 (4)		12 (7)	15 (9)	
Rarely	5 (2)	5 (2)		3 (2)	1 (0.6)		0 (0)	3 (2)	
From time to time	6 (2)	4 (1)		2 (1)	1 (0.6)		1 (0.6)	0 (0)	
Often	7 (3)	8 (3)		1 (0.6)	1 (0.6)		5 (3)	3 (2)	
Always	30 (11)	24 (8)		31 (19)	29 (18)		26 (15)	26 (16)	
Has not had sex	154 (55)	169 (58)		110 (68)	125 (76)		130 (75)	118 (70)	
Refusal	8 (3)	3 (1)		2 (1)	0 (0)		0 (0)	1 (0.6)	
Don't know	3 (1)	7 (2)	0.586	1 (0.6)	1 (0.6)	0.523	0 (0)	2 (1)	0.306

Participants in the CM arm also displayed a decrease in the burden of depression between the first, third, and fifth visit. At the first visit, 65 percent of participants indicated an absence of depression, 89 percent during the third visit, and 84 percent during the fifth visit. While still displaying an overall decrease, there was a slight increase exhibited between the third and fifth visit. At the first visit, 25 percent of participants in the CM arm experienced mild depression, 10 percent during the third visit, with a slight increase to 13 percent during the fifth visit. One percent of participants experienced moderately severe depression at the first visit, and no signs at the third and fifth visit. This figure demonstrates a slight increase in the proportion of depression between the third and fifth visits, with an overall decrease in its severity among both the SOC and CM arms.

Table 10 Mental health outcomes—12 months follow-up

	Visit 1			Visit 3			Visit 5		
	SOC (n=281) n (%)	CM (n=292) n (%)	p-value	SOC (n=163) n (%)	CM (n=165) n (%)	p-value	SOC (n=174) n (%)	CM (n=168) n (%)	p-value
None	179 (64)	189 (65)		135 (83)	147 (89)		152 (87)	141 (84)	
Mild	66 (24)	73 (25)		23 (14)	17 (10)		19 (11)	22 (13)	
Moderate	26 (9)	24 (8)		3 (2)	1 (0.6)		3 (2)	5 (3)	

Moderately severe	6 (2)	4 (1)		1 (0.6)	0 (0)		0 (0)	0 (0)	
Severe	2 (0.7)	1 (0.3)	0.880	0 (0)	0 (0)	0.336	0 (0)	0 (0)	0.598

Substance abuse

More than 90 percent of respondents at baseline, third, and fifth visits said they had never consumed alcohol in the last three months prior to the survey. Among SOC respondents, 5 percent reported having alcohol once a month at baseline, 6 percent at the third visit, and 4 percent at the fifth visit. The proportion of alcohol users is lower among participants in the case management arm than in those in the standard care arm. In addition, the proportion of alcohol users was higher on the third visit than in other visits.

Most CM participants surveyed in this study reported drinking up to three or four glasses of alcohol a day (44%) at the fifth visit. Those who consume one to two drinks per day represent 44 percent of this population. Those who have seven to nine drinks a day account for 11 percent.

The proportion of people in the SOC arm who have more than six drinks per day was not negligible, but there was a downward trend with progressive visits: 7 percent at baseline, 6 percent at the third visit, and 5.6 percent at the fifth visit. The proportion of people reporting drug injection in the last 3 months prior to the surveys was very low: 0.7 percent of SOC respondents at baseline, 0 percent at the third visit, and 2 percent at the fifth visit.

Antiretroviral therapy

Table 12 displays characteristics of ART medication including the percentage of participants initiating ART in the past 30 days, the ability to take ART medication, frequency of appropriate ART drug administration, and present use of medication.

The proportion of participants in the SOC arm who reported a very poor ability to take ART medication between the third and fifth visits increased from 0.6 percent to 3 percent. Those with a very good ability to take ART medication increased from 31 percent to 37 percent, and those with an excellent ability increased from 26 percent to 29 percent. In the CM arm, there was an increase from 1 percent to 2 percent in participants who reported a very poor ability to take ART medication. Participants with a good ability increased from 26 percent to 27 percent, and those with an excellent ability similarly decreased from 36 percent during the third visit to 29 percent during the fifth visit.

Participants were also asked to indicate how often ART medication was taken as required. At the third visit in the SOC group, 1 percent reported they never did, which increased to 2 percent at the fifth visit. Between the third and fifth visit there was a decrease from 16 percent to 1 percent in those who often took their ART medication when they were supposed to. There was a large increase among those who always took their ART medication when required, from 0.6 percent to 74 percent between third and fifth visits. Among the CM group, there was a reported increase from 3 percent to 4 percent in those who never took their medication. A decrease from 9 percent to 2 percent was displayed in those who often took their medication, and an increase from 0 percent to 73 percent in those who always displayed appropriately timed usage of ART

Table 11 Substance use among participants in study arms—12-month follow up

	Visit 1			Visit 3			Visit 5		
	SOC (n=281) n (%)	CM (n =292) n (%)	p-value	SOC (n =163) n (%)	CM (n =165) n (%)	p-value	SOC (n =174) n (%)	CM (n =168) n (%)	p-value
Alcohol consumption in last 3 months									
Never	252 (90)	277 (95)		145 (89)	152 (92)		156 (90)	159 (95)	
1 per month or less	14 (5)	7 (2)		9 (6)	8 (5)		7 (4)	6 (4)	
2–4 per month	5 (2)	3 (1)		3 (2)	3 (2)		5 (3)	1 (0.6)	
2–3 per week	2 (0.7)	4 (1)		2 (1)	1 (0.6)		2 (1)	0 (0)	
4 > per week	7 (3)	1 (0.3)		3 (2)	1 (0.6)		4 (2)	2 (1)	
Refusal	1 (0.4)	0 (0)	0.076	1 (0.6)	0 (0)	0.770	156 (90)	159 (95)	0.255
Standard glasses per day									
1–2	17 (61)	9 (60)		7 (41)	7 (54)		7 (39)	4 (44)	
3–4	5 (18)	4 (27)		7 (41)	2 (15)		8 (44)	4 (44)	
5–6	1 (4)	1 (7)		1 (6)	1 (8)		1 (6)	0 (0)	
7–9	2 (7)	1 (7)		1 (6)	1 (8)		1 (6)	1 (11)	
10 or more	2 (7)	0 (0)		1 (6)	1 (8)		1 (6)	0 (0)	
Don't know	1 (4)	0 (0)	0.825	0 (0)	1 (8)	0.653	7 (39)	4 (44)	0.862
6 standard glasses or more at a time									
Never	7 (25)	5 (33)		13 (77)	5 (39)		6 (33)	5 (56)	
Less than once per month	8 (29)	4 (27)		1 (6)	1 (8)		6 (33)	1 (11)	
Once per month	4 (14)	2 (13)		1 (6)	2 (15)		2 (11)	1 (11)	
Once per week	4 (14)	2 (13)		0 (0)	3 (23)		3 (17)	0 (0)	
Every day or almost every day	4 (14)	2 (13)		2 (12)	1 (8)		0 (0)	2 (22)	
Don't know	1 (4)	0 (0)	0.976	0 (0)	1 (8)	0.166	1 (6)	0 (0)	0.164
Ever used injection drugs	2 (0.7)	1 (0.3)	0.540	0 (0)	1 (0.6)	0.320	4 (2)	3 (2)	0.738

medication.

During both the third and fifth visits, 98 percent of participants in the SOC reported currently taking their ART medication. Similarly, in the CM group, 99 percent of participants reported current usage at the third visit; however, this percentage decreased to 98 percent during the fifth visit.

ART medication stockouts

Participants were asked to answer questions related to ART drugs stock outs at health facilities. In the SOC group, 20 percent reported that a health facility did not have the required ART drugs available since the time of study enrollment. Similarly, 24 percent reported a lack of ART drugs

in the CM group. Eighty percent and 75 percent did not report ART drugs stockouts at health facilities in the SOC and CM groups, respectively. Overall, 22 percent reported a lack of ART drugs at health facilities, while 78 percent did not experience a shortage of ART drugs.

The duration of stockouts was reported to be greater than two weeks among 31 percent of SOC participants. Twenty-nine percent of participants noted a stockout of 1–2 weeks, and 18 percent of participants reported a shortage that lasted 1–2 days or 3–6 days. Twenty-seven percent of participants in the CM arm also reported the greatest shortage of longer than two weeks, while 29 percent reported a duration of 3–6 days. Twenty-two percent of participants noted a stock out of both 1–2 days and 1–2 weeks. Overall, 28 percent of participants reported a stock out of longer than two weeks, 25 percent of 1–2 weeks, 24 percent of 3–6 days, and 20 percent of 1–2 days.

Overall, 33 percent of participants were referred elsewhere for ART drugs, while 67 percent were not provided with a referral. Specifically, 18 percent of participants in the SOC arm and 46 percent of participants in the CM arm were referred elsewhere.

Table 13 ART medication stockouts at health facilities

Table 12 Ability to take ART medication—12 months follow-up

	Visit 1			Visit 3			Visit 5		
	SOC (n=281) n (%)	CM (n=292) n (%)	p-value	SOC (n=163) n (%)	CM (n=165) n (%)	P-value	SOC (n=174) n (%)	CM (n=168) n (%)	p-value
Ability to take ART medication									
Very poor	1 (0.8)	6 (5)		1 (0.6)	2 (1)		5 (3)	4 (2)	
Poor	5 (41)	1 (0.7)		1 (0.6)	0 (0)		1 (0.6)	2 (1)	
Average	4 (3)	4 (3)		5 (3)	4 (3)		3 (2)	1 (0.6)	
Good	42 (35)	42 (31)		52 (33)	41 (26)		49 (29)	45 (27)	
Very good	37 (31)	37 (28)		59 (37)	55 (34)		64 (37)	65 (40)	
Excellent	31 (26)	43 (32)		41 (26)	57 (36)		50 (29)	47 (29)	
Don't know	1 (0.8)	1 (0.7)	0.274	0 (0)	1 (0.6)	0.370	0 (0)	1 (0.6)	0.860
ART medication taken as supposed to									
Never	5 (4)	9 (7)		2 (1)	4 (3)		4 (2)	6 (4)	
Rarely	4 (3)	1 (0.7)		4 (3)	3 (2)		2 (1)	0 (0)	
Sometimes	2 (2)	0 (0)		14 (9)	10 (6)		2 (1)	2 (1)	
Often	9 (7)	9 (7)		25 (16)	15 (9)		2 (1)	3 (2)	
Almost always	13 (11)	19 (14)		113 (71)	128 (80)		35 (20)	33 (20)	
Always	88 (73)	95 (71)		1 (0.6)	0 (0)		127 (74)	121 (73)	
Don't know	0 (0)	1 (0.7)	0.350	2 (1)	4 (3)	0.315	4 (2)	6 (4)	0.752
Are you currently taking your HIV medication?	117 (97)	127 (95)	0.452	157 (99)	159 (99)	0.558	170 (99)	161 (98)	0.381

	SOC (n=22) n (%)	CM (n=11) n (%)	Total (n=33) n (%)	p-value
ART drugs not available				
No	139 (80)	126 (75)	265 (78)	
Yes	34 (20)	41 (24)	75 (22)	
Refusal	0 (0)	1 (0.6)	1 (0.3)	
Don't know	1 (0.6)	0 (0)	1 (0.3)	0.364
Longest stock out (in days)				
1–2 days	6 (18)	9 (22)	15 (20)	
3–6 days	6 (18)	12 (29)	18 (24)	
1–2 weeks	10 (29)	9 (22)	19 (25)	
More than 2 weeks	10 (29)	11 (27)	21 (28)	
Don't know	2 (6)	0 (0)	2 (3)	0.395
Referred elsewhere				
No	28 (82)	22 (54)	50 (67)	
Yes	6 (17)	19 (46)	25 (33)	0.009

Intervention evaluation

Participants in the SOC (n=93) and CM (n=123) arms of the intervention were read a series of statements regarding their interactions with the case manager over the duration of the study. They were then asked to rate their reaction to the statement as one of five categories: strongly agree, agree, neither agree nor disagree (neutral), disagree, or strongly disagree. Questions referenced participant experiences and acceptability regarding in person interactions with the case manager as well as SMS and phone contact. Table 14 presents participant answers during the fifth visit, 12 months after initiation of the intervention.

When read the statement "I was satisfied with the case manager," 33 percent of SOC participants responded that they strongly agreed and 60 percent that they agreed. In the CM group the numbers were 30 percent and 65 percent, respectively. Ninety-five percent of SOC participants indicated that they either strongly agreed or agreed that they found the meetings with the case manager to be helpful, while 99 percent of CM participants had the same response. Additionally, 96 percent of SOC respondents indicated that they strongly agreed or agreed with the statement "I felt comfortable with my case manager," compared to 91 percent for the CM arm. Nineteen percent of the SOC arm and 15 percent of the CM arm responded that they agreed or strongly agreed with the statement "I don't find the meetings with the case manager to be important;" the percentage of those that strongly agreed was 5 percent in the SOC arm and 7 percent in the CM

group.

In both groups, most participants either disagreed or strongly disagreed with the statement "I don't think these meetings with my case manager had an impact on achieving my treatment objectives." Thirty-three percent of the SOC group and 28 percent of the CM group strongly disagreed with the statement, and 42 percent and 58 percent disagreed, respectively. Nineteen percent of the SOC group felt that they could not express themselves freely during meetings with their case manager, while 11 percent of CM participants responded in the same way.

Among the SOC arm respondents, 38 percent strongly agreed and 56 percent agreed that the meetings were presented in a way that made them sound interesting, while 37 percent and 59 percent of CM participants had the same answers, respectively. Ninety-five percent of SOC participants either agreed or strongly agreed that the case manager was knowledgeable about the topics discussed, and 96 percent of CM participants responded positively to this question. In both groups, a large majority agreed that the case manager had tried to understand their individual needs.

Participants were also read the statement "certain topics that I discussed with the case manager made me uncomfortable." Eighty-nine percent of the CM group and 90 percent of the SOC group either disagreed or strongly disagreed. Meanwhile, 5 percent of the CM group responded that they neither agreed not disagreed, and 5 percent agreed or strongly agreed. Among the SOC group, 5 percent either agreed or strongly agreed, and no respondents responded neutrally.

In both treatment groups no participants indicated that the case manager was not respectful of their choices, although 0.8 percent of the CM respondents indicated that they neither agreed nor disagreed with the statement. A majority of respondents in both groups (91%) said that they planned to attend future meetings with their case manager, representing 88 percent of SOC participants and 94 percent of CM participants.

Participants were also asked to respond to a number of questions regarding the feasibility and acceptability of implementing the proposed strategies. Thirty-nine percent of SOC respondents believed they had enough money to implement the proposed strategies (20% strongly agreed and 18% agreed), while 28 percent believed they do not (20% disagreed and 8% strongly disagreed). In the CM arm, meanwhile, 50 percent of respondents believed they have enough money (19% strongly agreed and 32% agreed), and 32 percent believed they do not (23% disagreed and 9% strongly disagreed). Similarly, participants were asked whether they believed they have the tools needed to implement the proposed strategies. Sixty-nine percent of SOC respondents believed they did (28% strongly agreed and 41% agreed), while 78 percent of CM participants responded positively (28% strongly agreed and 50% agreed). In both groups, a vast majority indicated that they either strongly agreed or agreed that they felt better equipped after the intervention (95% in the SOC group and 98% in the CM group).

In regard to expanding the program to all PLHIV, 95 percent of the SOC group and 98 percent of the CM group either strongly agreed or agreed that meetings with a case manager should be made available to all PLHIV. The percentage that either disagreed or strongly disagreed with the statement was 2 percent in both the SOC group and the CM group. Participants were also asked

whether they planned to share what they had learned in the meetings with other PLHIV. Ninety-five percent of the SOC group replied positively (45% strongly agreed and 50% agreed). The CM group also had a high positive response rate of 98 percent (42% strongly agreed and 55% agreed).

Table 14 Intervention implementation outcomes

	SOC (n=93) n (%)	CM (n=123) n (%)	Total (n=216) n (%)	p-value
I was satisfied with the case manager				
Strongly disagree	1 (1)	2 (2)	3 (1)	
Disagree	1 (1)	0 (0)	1 (0.5)	
Neutral	2 (2)	3 (2)	5 (2)	
Agree	56 (60)	80 (65)	136 (63)	
Strongly agree	31 (33)	37 (30)	68 (32)	
Refusal	0 (0)	1 (0.8)	1 (0.5)	
Don't know	2 (2)	0 (0)	2 (0.9)	0.514
I thought the meetings with the case manager took too long				
Strongly disagree	29 (31)	33 (27)	62 (29)	
Disagree	30 (32)	46 (37)	76 (35)	
Neutral	1 (1)	4 (3)	5 (2)	
Agree	18 (19)	22 (18)	40 (19)	
Strongly agree	13 (14)	16 (13)	29 (13)	
Refusal	0 (0)	1 (0.8)	1 (0.5)	
Don't know	2 (2)	1 (0.8)	3 (1)	0.761
I found the meeting with the case manager to be helpful				
Strongly disagree	1 (1)	0 (0)	1 (0.5)	
Disagree	2 (2)	0 (0)	2 (0.9)	
Neutral	1 (1)	0 (0)	1 (0.5)	
Agree	49 (53)	72 (59)	121 (56)	
Strongly agree	39 (42)	50 (41)	89 (41)	
Don't know	1 (1)	1 (0.8)	2 (0.9)	0.339
I felt comfortable with my case manager				
Disagree	1 (1)	1 (0.8)	2 (0.9)	
Neutral	1 (1)	1 (0.8)	2 (0.9)	
Agree	53 (57)	74 (60)	127 (59)	
Strongly agree	36 (39)	47 (38)	83 (38)	
Don't know	2 (2)	0 (0)	2 (0.9)	0.589
The strategies proposed by the case manager helped me be more observant of my treatment				
Neutral	0 (0)	1 (50)	1 (33)	
Agree	1 (100)	1 (50)	2 (67)	0.386
The discussion helped me accept that I am living with HIV				
Disagree	2 (2)	0 (0)	2 (0.9)	
Neutral	2 (2)	0 (0)	2 (0.9)	
Agree	54 (58)	74 (60)	128 (59)	
Strongly agree	34 (37)	48 (39)	82 (38)	
Refusal	0 (0)	1 (0.8)	1 (0.5)	
Don't know	1 (1)	0 (0)	1 (0.5)	0.186
I don't find the meetings with the case manager to be important				
Strongly disagree	32 (34.4)	39 (32)	71 (33)	
Disagree	39 (41.9)	61 (50)	100 (46)	
Neutral	2 (2.2)	2 (2)	4 (2)	
Agree	13 (14.0)	10 (8)	23 (11)	
Strongly agree	5 (5.4)	9 (7)	14 (7)	
Don't know	2 (2.2)	2 (2)	4 (2)	0.707
I believe I have enough money to implement the proposed strategies				
Strongly disagree	7 (7.5)	11 (9)	18 (8)	
Disagree	19 (20.4)	28 (23)	47 (22)	
Neutral	27 (29.0)	19 (15)	46 (21)	
Agree	17 (18.3)	39 (32)	56 (26)	
Strongly agree	19 (20.4)	23 (19)	42 (19)	
Refusal	1 (1)	1 (0.8)	2 (0.9)	
Don't know	3 (3)	2 (2)	5 (2)	0.161

I believe I have the tools I need to implement the proposed strategies				
Strongly disagree	1 (1)	4 (3)	5 (2)	
Disagree	7 (8)	5 (4)	12 (6)	
Neutral	17 (18)	16 (13)	33 (15)	
Agree	38 (41)	62 (50)	100 (46)	
Strongly agree	26 (28)	34 (28)	60 (28)	
Don't know	4 (4)	2 (2)	6 (3)	0.347
I think the location of these meetings with the case manager is too far away from where I live				
Strongly disagree	23 (25)	30 (24)	53 (25)	
Disagree	40 (43)	57 (46)	97 (45)	
Neutral	2 (2)	3 (2)	5 (2)	
Agree	18 (19)	25 (20)	43 (20)	
Strongly agree	9 (10)	7 (6)	16 (7)	
Don't know	1 (1)	1 (0.8)	2 (0.9)	0.929
I don't think these meetings with my case manager had an impact on achieving my treatment objectives				
Strongly disagree	31 (33)	34 (28)	65 (30)	
Disagree	39 (42)	71 (58)	110 (51)	
Neutral	2 (2)	2 (2)	4 (2)	
Agree	10 (11)	9 (7)	19 (9)	
Strongly agree	8 (9)	5 (4)	13 (6)	
Don't know	3 (3)	2 (2)	5 (2)	0.274
I sometimes felt that I could not express myself freely during these meetings				
Strongly disagree	29 (31)	39 (32)	68 (32)	
Disagree	44 (47)	60 (49)	104 (48)	
Neutral	1 (1)	2 (2)	3 (1)	
Agree	12 (13)	15 (12)	27 (13)	
Strongly agree	3 (3)	5 (4)	8 (4)	
Refusal	0 (0)	1 (0.8)	1 (0.5)	
Don't know	4 (4)	1 (0.8)	5 (2)	0.703
I plan on attending future meetings with my case manager				
Strongly disagree	1 (1)	2 (2)	3 (1)	
Disagree	5 (5)	2 (2)	7 (3)	
Neutral	3 (3)	3 (2)	6 (3)	
Agree	48 (52)	77 (63)	125 (58)	
Strongly agree	33 (36)	38 (31)	71 (33)	
Don't know	3 (3)	1 (0.8)	4 (2)	0.343
The meetings were presented in a way that made them sound interesting				
Disagree	0 (0)	2 (2)	2 (0.9)	
Neutral	3 (3)	1 (0.8)	4 (2)	
Agree	52 (56)	73 (59)	125 (58)	
Strongly agree	35 (38)	45 (37)	80 (37)	
Don't know	3 (3)	2 (2)	5 (2)	0.422
These meetings with a case manager should be made available to all PLHIV				
Strongly disagree	2 (2)	1 (0.8)	3 (1)	
Disagree	0 (0)	1 (0.8)	1 (0.5)	
Neutral	2 (2)	1 (0.8)	3 (1)	
Agree	46 (50)	68 (55)	114 (53)	
Strongly agree	42 (45)	52 (42)	94 (44)	
Don't know	1 (1)	0 (0)	1 (0.5)	0.566
I plan on sharing what I've learned in the meetings with other PLHIV				
Strongly disagree	4 (4)	5 (4)	9 (4)	
Disagree	3 (3)	17 (14)	20 (9)	
Neutral	1 (1)	2 (2)	3 (1)	
Agree	51 (55)	55 (45)	106 (49)	
Strongly agree	33 (36)	39 (32)	72 (33)	
Don't know	1 (1)	5 (4)	6 (3)	0.088

The case manager was knowledgeable about the topics we discussed				
Strongly disagree	0 (0)	1 (0.8)	1 (0.5)	
Neutral	0 (0)	1 (0.8)	1 (0.5)	
Agree	52 (56)	75 (61)	127 (59)	
Strongly agree	36 (39)	43 (35)	79 (37)	
Don't know	5 (5)	3 (2)	8 (4)	0.528
The case manager tried to understand my individuals needs				
Strongly disagree	1 (1)	0 (0)	1 (0.5)	
Disagree	0 (0)	1 (0.8)	1 (0.5)	
Neutral	1 (1)	1 (0.8)	2 (0.9)	
Agree	50 (54)	77 (63)	127 (59)	
Strongly agree	40 (43)	42 (34)	82 (38)	
Don't know	1 (1)	2 (2)	3 (1)	0.545
The case manager was respectful of my choices				
Neutral	0 (0)	1 (0.8)	1 (0.5)	
Agree	52 (56)	71 (58)	123 (57)	
Strongly agree	40 (43)	51 (42)	91 (42)	
Don't know	1 (1)	0 (0)	1 (0.5)	0.544
The case manager took my situation into account when proposing strategies				
Agree	14 (56)	27 (61)	41 (59)	
Strongly agree	11 (44)	17 (39)	28 (41)	0.663
The case manager referred me to the appropriate services				
Disagree	0 (0)	1 (8)	1 (7)	
Neutral	0 (0)	1 (8)	1 (7)	
Agree	1 (100)	8 (62)	9 (64)	
Strongly agree	0 (0)	3 (23)	3 (21)	0.897
I feel better equipped				
Disagree	2 (2)	0 (0)	2 (0.9)	
Neutral	1 (1)	2 (2)	3 (1)	
Agree	51 (55)	75 (61)	126 (58)	
Strongly agree	37 (40)	45 (37)	82 (38)	
Don't know	2 (2)	1 (0.8)	3 (1)	0.416
Certain topics that I discussed with the case manager made me uncomfortable				
Strongly disagree	32 (34)	39 (32)	71 (33)	
Disagree	52 (56)	70 (57)	122 (57)	
Neutral	0 (0)	6 (5)	6 (3)	
Agree	1 (1)	5 (4)	6 (3)	
Strongly agree	4 (4)	1 (0.8)	5 (2)	
Don't know	4 (4)	2 (2)	6 (3)	0.062
Overall, how would you rate your meetings with a case manager?				
Very poor	0 (0)	1 (0.8)	1 (0.5)	
Poor	0 (0)	1 (0.8)	1 (0.5)	
Average	3 (3)	4 (3)	7 (3)	
Good	52 (56)	59 (48)	111 (51)	
Very good	36 (39)	57 (46)	93 (43)	
Don't know	2 (2)	1 (0.8)	3 (1)	0.614
How easy or difficult was it for you to come here today?				
Not difficult at all	81 (87.)	106 (86)	187 (87)	
Somewhat difficult	7 (8)	11 (9)	18 (8)	
Very difficult	2 (2)	2 (2)	4 (2)	
Extremely difficult	3 (3)	1 (0.8)	4 (2)	
Don't know	0 (0)	3 (2)	3 (1)	0.387

Intervention sustainability

Reminding patients to take ART medication over the phone is often considered essential for patient adherence to treatment. In this study, almost all respondents in both arms reported they would continue taking ART medication without telephone reminders. Indeed, 46 percent of the SOC arm participants and 39 percent of those in the CM arm strongly agreed that they could do

so. Similarly, 50 percent of SOC participants and 57 percent in the CM arm agreed. Additionally, 95 percent of participants in SOC and 96 percent of those in CM believed they would adhere to treatment without case managers' intervention.

In contrast to those who reported taking ART medication without the intervention of case managers, a significant proportion of participants surveyed in both arms of the study appeared to still need the help of case managers to deal with other health-related problems. Indeed, 5 percent of SOC participants and 3 percent in CM disagreed or strongly disagreed that they could continue to manage their health problems independently.

Several participants in both arms of the study still felt they needed case managers' support to face daily health challenges. Eight percent of SOC participants and 5 percent of those in CM reported they could not overcome these challenges without the case managers' help. Eighty-three percent of SOC participants and 91 percent in CM would continue receiving support from the case manager if available.

Sixty-one percent of participants in both arms said they never stopped taking ART medication because of life events they were involved in during the study period, representing 59 percent of SOC participants and 64 percent of CM.

Sixty-one percent of participants in CM and 60 percent in SOC at the fifth visit reported continuing their ART therapy despite having difficulties attending their follow-up appointment. Over half of the participants in both arms of the study, 58 percent of participants in CM and 53 percent of participants in SOC, reported continuing treatment despite not seeing any improvement in their health.

Table 15 Intervention sustainability

	SOC (n=93) n (%)	CM (n=123) n (%)	Total (n=216) n (%)	P-value
Able to continue to take ART medication without regular calls from case manager				
Strongly disagree	3 (2)	5 (3)	8 (2)	
Disagree	1 (0.6)	0 (0)	1 (0.3)	
Neutral	2 (1)	0 (0)	2 (0.6)	
Agree	87 (50)	96 (57)	183 (54)	
Strongly agree	80 (46)	65 (39)	145 (42)	
Don't know	1 (0.6)	2 (1)	3 (0.9)	0.334
Able to continue to take your ART medication without regular SMS from case manager				
Strongly disagree	2 (1)	3 (2)	5 (2)	
Disagree	2 (1)	1 (0.6)	3 (0.9)	
Neutral	2 (1)	2 (1)	4 (1)	
Agree	88 (51)	98 (58)	186 (54)	
Strongly agree	79 (45)	63 (38)	142 (42)	
Don't know	1 (0.6)	1 (0.6)	2 (0.6)	0.735
Able to continue to take your ART medication without regular meetings with case manager				
Strongly disagree	3 (2)	1 (0.6)	4 (1)	
Disagree	1 (0.6)	1 (0.6)	2 (0.6)	
Neutral	3 (2)	2 (1)	5 (2)	
Agree	95 (55)	100 (60)	195 (57)	
Strongly agree	70 (40)	61 (36)	131 (38)	
Refusal	1 (0.6)	0 (0)	1 (0.3)	
Don't know	1 (0.6)	3 (2)	4 (1)	0.698
Capable of seeking supportive services for additional health challenges in the future				
Strongly disagree	1 (0.6)	1 (0.6)	2 (0.6)	
Disagree	7 (4)	4 (2)	11 (3)	
Neutral	5 (3)	6 (4)	11 (3)	
Agree	87 (50)	96 (57)	183 (54)	
Strongly agree	61 (35)	51 (30)	112 (33)	
Refusal	0 (0)	3 (2)	3 (0.9)	
Don't know	13 (8)	7 (4)	20 (6)	0.326
Capable of seeking supportive services for additional life challenges in the future				
Strongly disagree	3 (2)	2 (1)	5 (2)	
Disagree	11 (6)	6 (4)	17 (5)	
Neutral	7 (4)	5 (3)	12 (4)	
Agree	87 (50)	96 (57)	183 (54)	
Strongly agree	52 (30)	49 (29)	101 (30)	
Refusal	1 (0.6)	1 (0.6)	2 (0.6)	
Don't know	13 (8)	9 (5)	22 (6)	0.789
Continue with current support from case manager if available				
No	19 (11)	12 (7)	31 (9)	
Yes	144 (83)	152 (91)	296 (87)	
Refusal	1 (0.6)	1 (0.6)	2 (0.6)	
Don't know	10 (6)	3 (2)	13 (4)	0.141
Stick to treatment plan even when side effects interfere				
Cannot do at all	13 (8)	14 (8)	27 (8)	
Moderately certain can do	5 (3)	4 (2)	9 (3)	
Completely certain can do	92 (53)	92 (55)	184 (54)	
N/A: This has never happened to me before	64 (37)	57 (34)	121 (35)	
Don't know	0 (0)	1 (0.6)	1 (0.3)	0.836

Integrate treatment even if in front of people				
Cannot do at all	5 (3)	6 (4)	11 (3)	
Moderately certain can do	6 (3)	9 (5)	15 (4)	
Completely certain can do	96 (55)	96 (57)	192 (56)	
N/A: This has never happened to me before	66 (38)	56 (33)	122 (36)	
Refusal	1 (0.6)	0 (0)	1 (0.3)	
Don't know	0 (0)	1 (0.6)	1 (0.3)	0.638
Stick to treatment schedule when daily routine is disrupted				
Cannot do at all	3 (2)	2 (1)	5 (2)	
Moderately certain can do	11 (6)	7 (4)	18 (5)	
Completely certain can do	102 (59)	107 (64)	209 (61)	
N/A: This has never happened to me before	58 (33)	51 (30)	109 (32)	
Don't know	0 (0)	1 (0.6)	1 (0.3)	0.635
Stick to treatment schedule when not feeling well				
Cannot do at all	4 (2)	1 (0.6)	5 (2)	
Moderately certain can do	6 (3)	7 (4)	13 (4)	
Completely certain can do	103 (59)	107 (64)	210 (61)	
N/A: This has never happened to me before	61 (35)	50 (30)	111 (33)	
Don't know	0 (0)	3 (2)	3 (0.9)	0.204
Continue with treatment even if interferes with daily activities				
Cannot do at all	5 (3)	1 (0.6)	6 (2)	
Moderately certain can do	6 (3)	8 (5)	14 (4)	
Completely certain can do	113 (65)	108 (64)	221 (65)	
N/A: This has never happened to me before	50 (29)	48 (29)	98 (29)	
Don't know	0 (0)	3 (2)	3 (0.9)	0.199
Continue with treatment when feeling discouraged about health				
Cannot do at all	4 (2)	1 (0.6)	5 (2)	
Moderately certain can do	5 (3)	10 (6)	15 (4)	
Completely certain can do	99 (57)	104 (62)	203 (59)	
N/A: This has never happened to me before	66 (38)	51 (30)	117 (34)	
Don't know	0 (0)	2 (1)	2 (0.6)	0.116
Continue with treatment even when clinic appointments are a hassle				
Cannot do at all	3 (2)	2 (1)	5 (2)	
Moderately certain can do	5 (3)	9 (5)	14 (4)	
Completely certain can do	106 (61)	101 (60)	207 (61)	
N/A: This has never happened to me before	60 (35)	53 (32)	113 (33)	
Refusal	0 (0)	1 (0.6)	1 (0.3)	
Don't know	0 (0)	2 (1)	2 (0.6)	0.442
Continue with treatment when people close tell you it is not doing good				
Cannot do at all	2 (1)	2 (1)	4 (1)	
Moderately certain can do	7 (4)	6 (4)	13 (4)	
Completely certain can do	99 (57)	98 (58)	197 (58)	
N/A: This has never happened to me before	64 (37)	59 (35)	123 (2)	
Refusal	2 (1)	0 (0)	2 (0.6)	
Don't know	0 (0)	3 (2)	3 (0.9)	0.394
Stick to your treatment if the medication does not improve health				
Cannot do at all	4 (2)	1 (0.6)	5 (2)	
Moderately certain can do	5 (3)	3 (2)	8 (2)	
Completely certain can do	92 (53)	97 (58)	189 (55)	
N/A: This has never happened to me before	69 (40)	62 (37)	131 (38)	
Refusal	0 (0)	2 (1)	2 (0.6)	
Don't know	4 (2)	3 (2)	7 (2)	0.435

Effectiveness and durability of CM vs. SOC interventions focused on achieving SVS

Five hundred seventy-eight were PLHIV were recruited into the study at baseline. Of these, 292 (51%) were randomized into CM and 281 (49%) were randomized into SOC. Five participants from the baseline visit and five participants from the third visit were excluded from further analyses as their intervention randomization information were missing, thus the analyses were carried out as a modified Intention to Treat (mITT) analysis.

Results for the mITT and per protocol analyses for the effectiveness of CM program at visits 3 and 5 are presented in Table 16. Viral suppression did not differ significantly according to randomization group at visit 3 (77% in the SOC arm and 77% in the CM arm) and visit 5 (74% in the SOC arm and 70% in the CM arm). There was no evidence of the durability of viral load suppression among visit 3 respondents continuing in both arms.

Table 16 Effectiveness of study arms in achieving viral suppression

Proportion virally suppressed	Modified intention to treat			Per protocol		
	SOC	CM	Difference in proportion (95% CI)	SOC	CM	Difference in proportion (95% CI)
Month 6	77%	77%	-2.8% (-9.4%–8.8%)	81%	79%	-2.2% (-1.1%–6.5%)
Month 12	74%	70%	-4.5% (-1.4%–5.0%)	87%	84%	-3.5% (-1.2–4.5%)

While no participant characteristics were statistically significantly associated with viral suppression in the third visit, in the fifth visit, moderate depression was negatively associated with viral suppression (Table 17).

Table 17 Participant characteristics associated with viral suppression at visit 3 and visit 5

Characteristics	Visit 3		Visit 5	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Study arm				
SOC	Ref		Ref	0.303
CM	0.77 (0.42–1.40)	0.390	0.65 (0.29–1.47)	
Age	0.99 (0.96–1.03)	0.769	1.03 (0.99–1.07)	0.106
Biological sex				
Male	Ref		Ref	
Female	1.85 (0.51–6.67)	0.348	13.61 (2.55–72.6)	0.002
Gender Identity				
Male	Ref		Ref	
Female	1.51 (0.33–4.06)	0.827	0.16 (0.04–0.67)	0.012
Other	3.75 (0.76–18.5)	0.104	0.44 (0.88–2.33)	0.333
Education				
Less than primary education	Ref		Ref	
Primary education	0.93 (0.36–2.55)	0.881	0.71 (0.18–2.74)	0.621
Some/complete secondary education	1.12 (0.40–3.17)	0.826	0.99 (0.26–3.74)	0.987
Higher education	2.38 (0.57–9.98)	0.235	0.57 (0.10–3.28)	0.533
Other/refusal	2.66 (0.29–23.7)	0.380	0.10 (0.02–0.44)	0.002
Literacy				
Can't read or write in French or Wolof	Ref		Ref	
Can read or write in French or Wolof	1.40 (0.55–3.57)	0.477	0.77 (0.25–2.43)	0.663
Can read or write in both languages	1.03 (0.31–3.40)	0.966	3.39 (0.67–17.09)	0.139
Employment status				
Unemployed	Ref		Ref	
Employed	0.83 (0.41–1.69)	0.612	1.76 (0.63–4.86)	0.278
Student/Retired	1.02 (0.26–4.08)	0.967	3.78 (0.51–28.2)	0.194
Marital status				
Single/never married	Ref		Ref	
Married	1.49 (0.63–3.53)	0.359	1.34 (0.46–3.86)	0.593
Divorced/separated	2.21 (0.51–9.68)	0.289	–	
Widowed	1.02 (0.28–3.63)	0.981	0.26 (0.06–1.19)	0.082
Mental health (PHQ-9)				
None/minimal depression	Ref		Ref	
Mild depression	1.41 (0.56–2.81)	0.774	0.62 (0.21–1.91)	0.413
Moderate depression	—		0.05 (0.006–0.40)	0.005
Moderately severe/severe depression	—		—	
Any social stigma				
No	Ref		Ref	
Yes	0.77 (0.14–4.17)	0.757	0.36 (0.06–2.32)	0.283
Any healthcare stigma				
No	Ref		Ref	
Yes	1.46 (0.50–4.24)	0.294	2.24 (0.38–13.29)	0.376

Follow-up at visit 3 and 5

At the third visit, follow-up was 57 percent in the SOC arm and 53 percent in the CM arm, while at the fifth visit follow-up was 58 percent in the SOC arm and 55 percent in the CM arm. Associations with loss to follow-up are presented in Table 18. At the third visit, loss to follow-up was negatively associated with literacy in French and/or Wolof, being employed, or being a student or retiree, while identifying as neither male nor female was positively associated with loss to follow-up. Similar associations were observed in the fifth study visit where having symptoms of moderately severe to severe depression at baseline was also found to positively associated with being lost to follow-up ($p < 0.1$).

Cost effectiveness of CM approach

Cost-effectiveness analyses were not performed. Results for the mITT and per protocol analyses for the effectiveness of CM intervention at the third and fifth visits indicate no significant difference in viral suppression, thus no gain in health for the intervention group compared to the control group.

Table 18 Loss to follow-up accounting for baseline characteristics

Characteristics	Visit 3		Visit 5	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Study arm				
SOC	Ref		Ref	
CM	1.16 (0.82-1.64)	0.405	1.08 (0.77-1.53)	0.642
Age	1.00 (0.98-1.01)	0.620	0.98 (0.97-1.00)	0.071
Sex at birth				
Male	Ref		Ref	
Female	0.67 (0.20-2.30)	0.529	1.75 (0.48-6.34)	0.393
Gender identity				
Male	Ref		Ref	
Female	1.05 (0.32-3.42)	0.932	0.40 (0.11-1.40)	0.151
Other	2.08 (0.93-2.30)	0.076	2.16 (0.97-4.8)	0.059
Education				
Less than primary education	Ref		Ref	
Primary education	1.24 (0.66-2.32)	0.502	0.99 (0.53-1.84)	0.970
Some/complete secondary education	1.48 (0.81-2.70)	0.200	1.25 (0.70-2.27)	0.452
Higher education	1.19 (0.49-2.91)	0.702	1.45 (0.62-3.39)	0.385
Other/refusal	2.05 (0.86-4.93)	0.380	1.15 (0.50-2.64)	0.737
Literacy				
Can't read or write in French or Wolof	Ref		Ref	
Can read or write in French or Wolof	0.55 (0.33-0.93)	0.026	0.59 (0.35-0.99)	0.046
Can read or write in both languages	0.25 (0.11-0.53)	<0.001	0.37 (0.18-0.79)	0.009
Employment status				
Unemployed	Ref		Ref	
Employed	0.57 (0.37-0.87)	0.008	0.78 (0.51-1.18)	0.235
Student/retired	0.43 (0.17-1.08)	0.073	0.33 (0.13-0.82)	0.018
Marital status				
Single/never married	Ref		Ref	
Married	1.48 (0.89-2.48)	0.133	1.11 (0.66-1.85)	0..681
Divorced/separated	1.73 (0.81-3.70)	0.160	1.44 (0.67-3.06)	0.346
Widowed	1.73 (0.84-3.57)	0.139	1.45 (0.71-2.96)	0.312
Mental health (PHQ-9)				
None/minimal depression	Ref		Ref	
Mild depression	0.84 (0.56-1.28)	0.431	1.07 (0.70-1.60)	0.762
Moderate depression	0.76 (0.41-1.42)	0.386	0.68 (0.36-1.28)	0.231
Moderately severe/severe depression	0.64 (0.19-2.20)		0.32 (0.08-1.21)	0.093

AIM 4: BIOMETRIC FOLLOW-UP SYSTEM

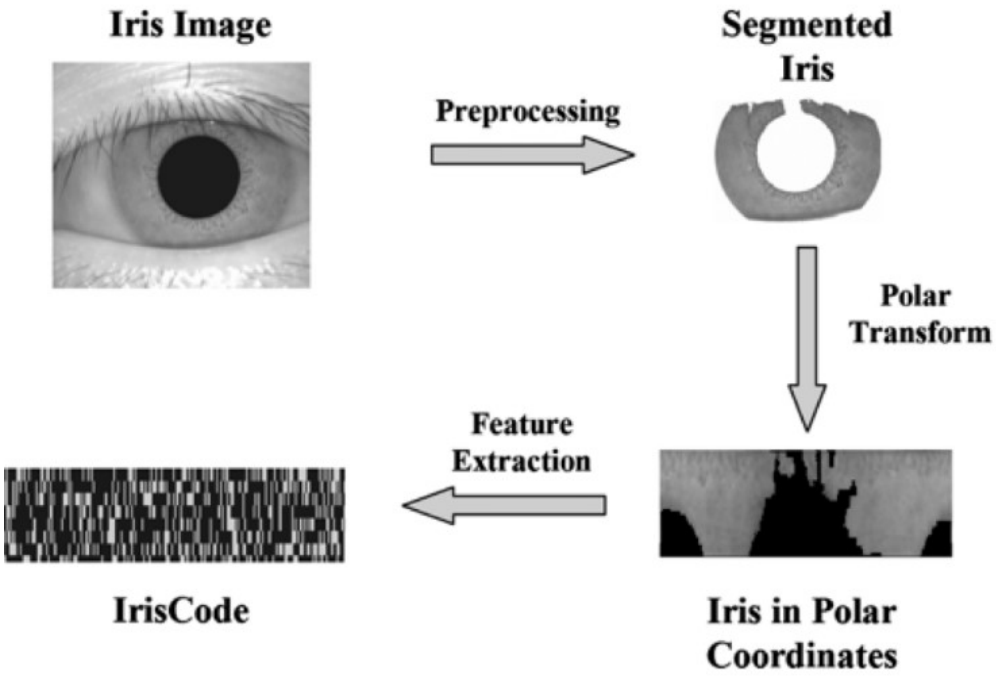
Overview

Iris scanning was used as a way to track participants and was focused on supporting evaluation of retention in ART. Preliminarily, the iris scanners and a laptop were placed in the study sites in Dakar and Ziguinchor, and all participants who initiated ART at these facilities had an iris scan as a means of registering into the study. It is these same facilities that are included as referral facilities for the HIVST.

The iris scanner was used with patients; however, the image of the iris was not stored. Rather, the image was converted into a 12-digit numerical code, which was stored in the electronic health record. The iRespond system was used for this study (http://irespond.org/). The iris scanners used were the BMT-20, which is a binoculars-type iris biometrics imaging device. The scanners were purchased through the iRespond's partner and biometric technology manufacturer CMITech.

The iris scanner captured an image of the iris, and the iris camera then used USB 2.0 (500 mAh) to transfer images to a laptop/tablet. It sent the photo to the software, which converted it to a global 12-digit numerical code and also generated a QR code. The iRespond software was encrypted, and no raw biometric images were stored. BitLocker full disk encryption was provided for protection of data on the device if it is stolen or lost. The image was converted through a binary template to ensure no potential for back-conversion (Figure 11). The Android tablets were used to scan the QR code, which then entered the 12-digit code along with the survey data.

Figure 11 Iris conversion



Methods

The unique 12-digit numeric code generated through the iris scanner was connected to the study data collection platform, SurveyCTO. On at least a weekly basis, study staff ensured that these databases were synced across study sites to minimize potential for loss to follow-up. The survey and biologic data were stored separately by the study team, online, though will be linkable via the 12-digit numeric code generated from the iris scan. The linking of these data did not happen at the clinic level to maximize safety and privacy of the individual.

Sample size

Sample size and all associated calculations were the same for the biometric follow-up system as for the CM vs. SOC portions of the study, given that this study was conducted with the same participants as those in the CM vs. SOC cohorts.

Participants and recruitment

The biometric follow-up system intervention was conducted with participants in the CM vs. SOC cohorts. Therefore, the eligibility criteria were the same for the biometric follow-up system intervention as the CM vs. SOC intervention, and no additional participants were included in biometric follow-up system intervention who were not included in the CM vs. SOC.

Inclusion criteria

- 18 years of age or older
- Mentally sound and capable of providing consent to participate
- Agrees to complete HIV and syphilis testing
- Speaks either French, Wolof, or both
- Provided informed consent to participate in the study
- Resident of Senegal for the past 3 months
- Intention to live in Dakar or Ziguinchor for the next 12 months
- Agrees to complete all required biological testing described in the consent form and receive results
- Enrolled in the CM vs. SOC cohort

Exclusion criteria

- Under 18 years of age
- Demonstrates mental incapacity, under the influence of substances, or any other illness preventing comprehension of the study procedures and informed consent
- Does not agree to complete all required biological testing described in the consent form or receive results

- Has not provided informed consent to participate in the study
- Not enrolled in the CM vs. SOC cohort

Recruitment process

The biometric follow-up intervention was only conducted among participants in the CM vs. SOC cohorts. At the point of enrollment, the trained study staff used the iris scanner to scan the participant's iris in order to generate the unique 12-digit numeric identification. With this, separate recruitment did not take place for Aim 4: Biometric follow-up system.

Consent process

Iris scanning was a mandatory component for enrollment into the study; therefore, if a participant did not consent to the use of iris_scanning, they were not enrolled into the study. However, we included the alternatives section in the consent form for discussion with the participant if they were unable or unwilling to provide full and informed consent. This alternatives section discussed options for receiving care and treatment in the health facilities without participating in the study. If the participant opted out of participating in the study, they were referred back to the health facility staff and provided the opportunity to enroll in treatment, which is the standard of care for treatment in Senegal, and identical to the control arm of the study. This treatment included STI testing (HIV testing would have already been done), counseling, and treatment. If a participant retracted their consent after initial enrollment, they were offered standard of care treatment

Study implementation and data collection

Once enrolled into the study, study staff scanned the participant's iris using the iris recognition. The iris scanner did not store the image of the iris, but rather, the image was converted into a 12-digit numerical code, which was stored in the data collection platform. The iris scanner captured an image of the iris, and the iris camera then used USB 2.0 (500 mAh) to transfer images to a laptop/tablet. It sent the photo to the software, which converted it to a global 12-digit numerical code and also generated a QR code. Android tablets were used to scan the QR code, which then entered the 12-didit code along with the survey data. There was also an option to send the code to the printer and print out the 12-digit code for the paper and lab forms.

The unique 12-digit numeric code generated through the iris scanner was connected to the study data collection platform, SurveyCTO. On at least a weekly basis, study staff ensured that these databases were synced across study sites to minimize potential for loss to follow-up. The survey and biologic data were stored separately by the study team, online, though will be linkable via the 12-digit numeric code generated from the iris scanning. The linking of these data did not happen at the clinic level to maximize safety and privacy of the individual.

The iris was scanned at each study visit to identify the participant and link the information obtained from the study visit to the previous information collected.

The iris image was not be stored, the data collection forms did not record personal identifiers connecting study participants, and there were no codes providing a link.

Data analysis

Implementation outcomes were used to evaluate uptake, routinization, acceptability, and long-term feasibility. Implementation results were used to inform the potential for the scale up of the use of iris scanning as a biometric follow-up system in measurement of retention support for PLHIV.

Results

When asked whether the iris scanner worked from the first trial or after several trials, patients in both arms of the study at baseline (n=49), at visit 3 (n=115), and at visit 5 (n=171) were asked whether the scanner always worked. From the first trial it worked in more than 77 percent of cases, 78 percent at baseline, 81 percent at visit 3, and 80 percent at visit 5. However, in 22; 11 and 16 percent of the cases for the CM arm, respectively at baseline, visit 3, and visit 5, it took several tries to make it work.

One goal of this part of the study was to determine if the use of the iris scanner made patients feel uncomfortable while using it. Responses obtained from patients at inclusion in visit 3 and 5 show that more than 83 percent of the patients found it comfortable or very comfortable to use, with a slight difference depending on the visit.

The current trend is toward increasing computerization of health activities to facilitate and make coding and monitoring more reliable. Within the framework of this study, the evaluation of the acceptability of using iris scanners as a strategy for identifying and monitoring HIV-positive patients was done at all visits. At baseline (n=49), visit 3 (n=115), and visit 5 (n=171), more than 90 percent of patients felt that the iris scanner was acceptable or very acceptable in their identification and follow-up. This rate of acceptability in identification for the CM participants was slightly higher at M6 (98%), then at M12 (93%) and at M0 (87%).

Patient satisfaction with the use of the iris scanner was very high. More than 90 percent of them reported being satisfied or very satisfied with the use of the device. Those who were very satisfied were more numerous at M0 (25%), than at M6 (11%) and M12 (18%).

Use of the iris scanner was never difficult according to 77 percent of SOC participants at baseline, 97 percent at visit 3, and 94 percent at visit 5. The rare cases of difficulty were more present at baseline, with 7 percent of cases reporting it as very difficult or extremely difficult.

As for acceptance to use the iris scanner in the future, only 4 percent of participants in the CM arm surveyed at visit 5 said they would refuse to use it. More than 94 percent agreed to use it in the future.

Table 19 Iris scanning—acceptability and uptake

	Visit 1			Visit 3			Visit 5		
	SOC (n=26) n (%)	CM (n=23) n (%)	p-value	SOC (n=60) n (%)	CM (n=55) n (%)	p-value	SOC (n=85) n (%)	CM (n=86) n (%)	p-value
Easy or difficult to use									
Not difficult at all	20 (77)	16 (70)		58 (97)	51 (93)		80 (94)	76 (88)	
Somewhat difficult	4 (15)	3 (13)		2 (3)	2 (4)		5 (6)	5 (6)	
Very difficult	0 (0)	1 (4)		0 (0)	0 (0)		0 (0)	4 (5)	
Extremely difficult	1 (4)	1 (4)		0 (0)	2 (4)		0 (0)	0 (0)	
Refusal	1 (4)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
Don't know	0 (0)	2 (9)	0.491	0 (0)	0 (0)	0.327	0 (0)	1 (1)	0.165
Physically comfortable to use									
Very uncomfortable	0 (0)	2 (9)		0 (0)	1 (2)		0 (0)	0 (0)	
Uncomfortable	1 (4)	2 (9)		1 (2)	0 (0)		0 (0)	3 (4)	
Neither comfortable nor uncomfortable	13 (50)	13 (57)		3 (5)	1 (2)		5 (6)	3 (4)	
Comfortable	11 (42)	6 (26)		48 (80)	42 (76)		57 (67)	63 (73)	
Very comfortable	1 (4)	0 (0)		8 (13)	11 (20)		23 (27)	16 (19)	
Refusal	0 (0)	2 (9)		0 (0)	0 (0)		0 (0)	1 (1)	
Don't know	1 (4)	2 (9)	0.327	0 (0)	0 (0)	0.453	0 (0.)	0 (0)	0.195
Psychologically comfortable to use									
Very uncomfortable	0 (0)	1 (4)		1 (2)	1 (2)		0 (0)	1 (1)	
Uncomfortable	2 (8)	2 (9)		4 (7)	1 (2)		2 (2)	4 (5)	
Neither comfortable nor uncomfortable	1 (4)	2 (9)		39 (65)	42 (76)		4 (5)	3 (4)	
Comfortable	7 (27)	13 (57)		16 (27)	11 (20)		58 (68)	54 (63)	
Very comfortable	16 (62)	5 (22)		1 (2)	1 (2)		21 (25)	24 (28)	
Refusal	0 (0)	1 (4)		4 (7)	1 (2)		0 (0)	1 (1)	
Don't know	2 (8)	2 (9)	0.068	39 (65)	42 (76)	0.453	2 (2)	4 (5)	0.709
Satisfied with use									
Very dissatisfied	1 (4)	0 (0)		0 (0)	0 (0)		0 (0)	1 (1)	
Dissatisfied	1 (4)	2 (9)		1 (2)	0 (0)		0 (0)	3 (4)	
Neither dissatisfied nor satisfied	15 (58)	18 (78)		2 (3)	2 (4)		2 (2)	3 (4)	
Satisfied	9 (35)	3 (13)		50 (83)	47 (86)		67 (79)	65 (76)	
Very satisfied	1 (4)	0 (0)		7 (12)	6 (11)		16 (19)	14 (16)	
Refusal	1 (4)	2 (9)		0 (0)	0 (0)		0 (0)	0 (0)	
Don't know	15 (58)	18 (78.)	0.218	0 (0)	0 (0)	0.812	0 (0)	0 (0)	0.360
Willingness to use									
No	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	3 (4)	
Yes	24 (92)	23 (100)		59 (98)	54 (98)		85 (100)	81 (94)	
Refusal	1 (4)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
Don't know	1 (4)	0 (0)	0.398	1 (2)	1 (2)	0.950	0 (0)	2 (2)	0.078

Table 20 Iris scanning—routinization and long-term feasibility

	Visit 1			Visit 3			Visit 5		
	SOC (n=26) n (%)	CM (n=23) n (%)	p-value	SOC (n=60) n (%)	CM (n=55) n (%)	p-value	SOC (n=85) n (%)	CM (n=86) n (%)	p-value
Worked on first attempt or more than once									
It worked the first attempt	22 (85)	16 (70)		44 (73)	49 (89)		68 (80)	68 (79)	
I need to try several times for it to work	0 (0)	5 (22)		13 (22)	6 (11)		15 (18)	14 (16)	
I tried several times and it never worked	4 (15)	2 (9)		3 (5)	0 (0)		2 (2)	4 (5)	
Refusal	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
Don't know	0 (0)	0 (0)	0.040	0 (0)	0 (0)	0.060	0 (0)	0 (0)	0.706
To identify patients in healthcare settings									
Very unacceptable	0 (0)	0 (0)		0 (0)	0 (0)		1 (1)	0 (0)	
Unacceptable	0 (0)	1 (4)		0 (0)	0 (0)		0 (0)	3 (4)	
Neither acceptable nor unacceptable	1 (4)	1 (4)		3 (5)	1 (2)		3 (4)	3 (4)	
Acceptable	15 (58)	14 (61)		49 (82)	45 (82)		62 (73)	64 (74)	
Very acceptable	10 (39)	6 (26)		8 (13)	9 (16)		18 (21)	16 (19)	
Refusal	0 (0)	1 (4)		0 (0)	0 (0)		1 (1)	0 (0)	
Don't know	0 (0)	0 (0)	0.581	0 (0)	0 (0)	0.602	1 (1)	0 (0)	0.399
To follow-up patient in healthcare settings									
Very unacceptable	0 (0)	0 (0)		0 (0)	0 (0)		1 (1)	0 (0)	
Unacceptable	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	3 (4)	
Neither acceptable nor unacceptable	1 (4)	1 (4)		3 (5)	1 (2)		3 (4)	3 (4)	
Acceptable	15 (58)	14 (61)		50 (83)	46 (84)		64 (75)	64 (74)	
Very acceptable	10 (39)	7 (30)		7 (12)	8 (15)		16 (19)	16 (19)	
Don't know	0 (0)	1 (4)		0 (0)	0 (0)		1 (1)	0 (0)	
Refusal	0 (0)	0 (0)	0.709	0 (0)	0 (0)	0.601	1 (1)	0 (0)	0.417
Best way to identify and follow-up patients in the future									
Iris scanning	19 (73)	13 (57)		49 (82)	34 (62)		67 (79)	64 (74)	
Unique ID questions	4 (15)	7 (30)		9 (15)	18 (33)		13 (15)	21 (24)	
Another way	1 (4)	1 (4)		1 (2)	2 (4)		3 (4)	1 (1)	
Refusal	1 (4)	0 (0)		0 (0)	1 (2)		2 (2)	0 (0)	
Don't know	1 (4)	2 (9)	0.540	1 (2)	0 (0)	0.098	67 (79)	64 (74)	0.176

LIMITATIONS

IMPLEMENTATION

This study was conducted in government facilities, with case management and treatment provision led by government health facility staff. We consider this study design and implementation strategy to be a strength of the study, in that it aims to assess the potential effectiveness of an intervention in a manner which would best represent implementation and potential scale up through the existing infrastructure and led by the Ministry of Health. However, this strategy is subject to limited resources, including staff with high workload and limited availability, representing the existing infrastructure available to implement the interventions. Additionally, the study was subject to stock outs and shortages of viral load testing, ART, and laboratory equipment. Throughout the study, there were periods in which resource constraints and reagent availability were limited and affected the ability to offer universal viral load testing at each designated period. These challenges may have influenced the implementation of the intervention, appropriate provision of care and ART, and the measurement of outcomes.

HIVST

Several limitations should be considered in this study. Participation in the pre- and post-test questionnaires was voluntary and may not represent the full sample of individuals who participated in HIVST distribution. The results may therefore be subject to selection bias. Participants who received HIVST through network distribution were not captured in data collection and are not represented in this analysis. Disclosure of key population status as well as positive reactivity from the HIVST were low in self-reported measures of this study. The distribution strategy prioritized members of key populations and worked closely with existing programs providing services to these populations. However, only one-third of the study sample self-reported key population status. Therefore, it may be that HIVST reached individuals who may not currently be at high risk of HIV, in which case there is a need to consider strategies to more effectively target key populations. Alternatively, key population status may have been underreported, in which case HIVST was able to reach individuals unwilling to disclose their key population-related behavior and less integrated into the key population networks. Additionally, there was a discrepancy between the proportion of reactive HIVST collected at the distribution sites and those who self-reported reactive results during post-test questionnaire. Although these figures cannot be linked or compared directly, it may suggest either underreporting of reactive test results, or possibly greater loss to follow-up for post-test questionnaires among individuals with a reactive HIVST.

CONCLUSION

This study was the first HIVST pilot study conducted in Senegal describing HIVST acceptability and feasibility for HIV testing in the most at-risk populations. HIVST is a complementary approach to current testing strategies, particularly with the most at-risk populations. Self-testing can potentially overcome barriers to HIV testing uptake by placing the locus of control on testing on the individual, increasing confidentiality, and allowing members of stigmatized groups to test in settings of privacy, safety, and with dignity. The study was successful in reaching first-time testers, including a large proportion of men, young people, and people who did not traditionally access HIV services.

Sustained collaboration with government and stakeholders is needed to facilitate self-test implementation, scale-up, and linkages to care in Senegal. The distribution of the self-test kits relied heavily on existing sites and networks. These results have made it possible to define strategies for distributing HIVST to the populations most affected by HIV for various projects currently being implemented in Senegal and West Africa.

CM approaches build on cognitive behavioral theory and help address barriers to treatment uptake, adherence, and retention. The intervention, through capacity building of case managers, aimed to improve patients' adherence to treatment, and hence viral load results. Case managers provided personalized support for health care services navigation, engagement in care, and treatment adherence. Although the study did not find a significant difference in the viral load results between the two arms at the end of the study, an improvement in viral load results was observed over time. Further analyses will be conducted to elucidate the factors associated with these outcomes.

Most participants reported being satisfied with their sessions. After the 12-month follow-up, participants stated that the meetings impacted the achievement of their treatment goals and that they felt better equipped. It should be noted that a team of health professionals supported the case managers on each site. Proper integration of case managers and enhancement of their role in the structure benefits both healthcare providers and patients. The role of case managers remains essential in the follow-up and retention in care of PLHIV.

The use of UIC for measuring patient retention remains essential in the context of HIV programs. Biometric follow-up systems such as fingerprints and the iris scanner represent an alternative to traditional follow-up systems. These are easy to use and offer an additional level of privacy, and the likelihood of duplicates is relatively low.

The iris scanner was introduced as a tool to measure participants' retention in the study. Participants declared the technology easy to use and acceptable for identifying and monitoring patients. They also reported it as the preferred method for generating a UIC. The iris scanner thus represents an alternative strategy in a context where key populations are hidden and mobile, allowing for better monitoring and also avoiding duplication of codes.

RECOMMENDATIONS

- The results from the study demonstrate that HIVST provides a complementary approach to reach populations who may face barriers to engagement with existing and routine HIV testing services. Primarily, this includes key populations and first-time testers. The study also highlights the importance of leveraging existing venues and networks for the distribution of HIVST kits. Sustained engagement with government and stakeholders is needed to facilitate the implementation and scale-up of HIVST and subsequent linkage to care in Senegal. Preliminary results from this study guided the development of national HIVST guidelines. Senegal has moved forward with recommending it as an additional approach to testing priority populations, including key populations, based on the study's preliminary results.
- Among participants with a reactive HIVST, 58 percent went for confirmatory testing, and among those with an invalid test result, none went for follow-up testing. Follow-up in this context is a challenge. Implementation of HIVST should include specific strategies for confirmatory testing, thus ensuring effective linkage to care for newly HIV diagnosed individuals.
- Patient monitoring in Senegal remains a challenge for the national ART program, especially during the agricultural season with patients absent over a long period. Study participant follow-up was equally impacted, with participants not attending all study visits. Specific strategies to overcome this barrier could include strengthening of regional and cross-border referral and counter-referral systems between health facilities.
- The intervention aimed to improve PLHIV's adherence to treatment by building the capacity of case managers and providing them with appropriate tools to facilitate support. Case managers appreciated the additional trainings and new strategies to improve the health of their peers. Study participants also expressed satisfaction with the case managers' skills, which significantly improved the quality of the interventions. Therefore, a continued strengthening of the case managers' capacity is recommended, with an emphasis on support, therapeutic education of the patient, and provision of adequate tools. In the absence of a close psychological follow-up, the case manager may provide psychological and moral support.
- The integration of case managers and a revaluation of their role in the structure benefit both health care providers and patients. On some sites, their role went beyond merely providing support to their peers living with HIV. They also assisted health care providers in providing primary care to other patients. Having case managers taking care of different categories of patients helps with confidentiality for PLHIV.
- The iris scanner is an acceptable biometric technology for monitoring PLHIV. Most study participants found it easy and comfortable to use. The use of the scanner still requires the installation of additional devices, including a computer and a tablet, as well as a stable internet connection. Thus, field staff must receive adequate training on its use and maintenance to minimize interruptions and other technical difficulties that may impact visits negatively. Also, designing culturally appropriate messages can increase the uptake of the scanner and reassure patients.
- Regular patient follow-up was challenging at different times of the study. As an example, in Ziguinchor, several participants missed study visits, as they were traveling to villages away

from health centers and often returning for their visits at the end of the agricultural season (which lasts between four and five months). This seasonal migration illustrates the importance of having advanced strategies for improving access to health care in rural areas. This issue is not specific to the study, and it impacts the national health system, causing many patients to drop out of care and treatment. In Senegal, national directives recommend the delivery of doses covering a period of up to three months in the event of a prolonged absence. Thus, the plan developed by the case manager could include telephone calls for a closer follow-up of the individual's state of health and treatment adherence. Establishing adherence clubs in remote areas could improve support and medication intake. A one-stop-shop model, with the provision of various health care services, including HIV care, could also be established. Finally, promoting and strengthening regional and cross-border referral and counter-referral systems between health facilities could facilitate access to care. All these strategies must consider the confidentiality of patients living with HIV.

- Some participants reported having felt different forms of stigma from the community and uniformed officers because of their sexual practices. However, they reported less stigma from health professionals. Numerous interventions were carried out within health centers before the study to facilitate access to care for PLHIV, particularly key populations. Community and police-level interventions remain necessary to reduce stigma. Communication strategies addressing HIV-related stigma, specifically through renewed investments in advocacy campaigns targeting opinion leaders, including the media and religious leaders, are needed to act on the social environment.
- Most study participants reported having felt no stigma in healthcare settings. The MOH implemented various trainings on treatment and care of PLHIV, including specifically for key populations. In comparison to earlier studies on these same sites, this may suggest a decrease of stigma in these settings, but it requires in-depth analysis to study the underlying factors impacting the indicators of stigma.
- Throughout the study, sites experienced stockouts of ART medication and viral load reagents, causing delays in treatment initiation and interruption and thus affecting the participants' health outcomes. Consequently, participants were referred to other health structures. This component should be evaluated before any implementation of a Test and Start strategy.

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Population Council
4301 Connecticut Ave, NW,
Suite 280
Washington, D.C. 20008 USA
Tel: +1 202 237 9400
Fax: +1 202 237 8410

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